Method of Levels therapy for psychosis

A thesis submitted to the University of Manchester for the degree of Doctor of Clinical Psychology (ClinPsyD) in the Faculty of Biology, Medicine and Health

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Glossary of Acronyms

B_Dist	Baseline Distress
B_Freq	Baseline Frequency
B1	Baseline at week 1
B2	Baseline at week 2
C.SRS	Child/Session Rating Scale
CAPE	Community Assessment of Psychic Experiences
CBT	Cognitive Behavioural Therapy
CMHT	Community Mental Health Team
CORE-OM	Clinical Outcomes in Routine Evaluation
COVID	Corona Virus Disease
DASS	Depression, Anxiety, Stress Scale
FU	Follow-up
FU_dist	Follow-up distress
FU_freq	Follow up frequency
GBO	The Goal-Based Outcome Measure
GCE	General Certificate of Education
GEL	Good Enough Level
GHQ-12	The General Health Questionnaire-12
HRA	Health Research Authority
MOL	Method of Levels
NICE	National Institute of Clinical Excellence
ORS	Outcome Rating Scale

PCT	Perceptual Control Theory
PSYCHLOPS	Psychological Outcome Profiles
PT	Post-therapy
PT_Diss	Post-therapy distress
PT_Freq	Post-therapy frequency
QPR	Questionnaire about the Process of Recovery
RCT	Randomized Clinical Trial
ROC	Reorganisation of Conflict Scale
SRS	Session Rating Scale
T	Therapy session
TAU	Treatment as Usual
YES	The Youth Empowerment Scale
YP-CORE	The Young Person's Clinical Outcomes in Routine Evaluation

Thesis Abstract

Method of Levels therapy for psychosis

Jadwiga Maria Nazimek

A thesis submitted to the University of Manchester
for the Degree of Doctor of Clinical Psychology, May 2020

The aim of this thesis was to explore potential effectiveness of Method of Levels (MOL) therapy for people experiencing psychosis. The thesis consists of three papers. Paper one is a systematic literature review of client-led appointment scheduling in psychological therapies. The narrative synthesis of results of 16 studies revealed that when clients schedule their own appointments, the majority attend a smaller number of sessions (between one and seven on average) than the number of sessions offered by the services; non-attendance rates are lower compared to interventions with prescribed numbers of sessions; therapy reduces symptoms; and clients perceive the interventions as useful.

Paper two is an empirical investigation of potential effectiveness of MOL therapy for people experiencing psychosis. A case series of MOL therapy was conducted with six participants with psychosis in secondary mental health care. Participants were offered therapy within a three-month timeframe, during which they were in charge of scheduling their own appointments and deciding on the content of sessions. An A-B with follow-up design was employed. Participants attended eight sessions of therapy on average. Analysis of reliable and clinically significant change indicated that five out of six participants improved and four recovered, as measured by Outcome Rating Scale, although four participants showed improvement before therapy commencedThere was little evidence of change in the measure of psychotic symptoms. The findings of this case series suggest that MOL therapy can be useful to people experiencing psychosis.

Paper three is a critical reflection on the work involved in the completion of this research project. It expands on the details and decision-making processes, and discusses the strengths, limitations, and implications of the project. Paper three concludes with personal reflection on the current research study.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Copyright statement

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Paper 1: Client-led appointment scheduling in psychological therapy.

This paper has been prepared in accordance with the author guidelines of Clinical Psychology Review (Appendix A)

Client-led appointment scheduling in psychological therapy.

A review of the literature.

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Abstract

To date, the optimum number of sessions required for psychological interventions has not been established. The number and frequency of psychological therapy appointments are usually determined in an arbitrary manner through research, national guidelines, and clinicians' individual judgement. Clinical services and research studies report high levels of client non-attendance and treatment dropout, resulting in wasted resources. Yet, some researchers argue that termination of therapy, perceived by services as premature, could be a cessation following a good enough level of change as perceived by clients. The current review examined the impact of client-led scheduling on the following clinical outcomes: attendance, change in symptoms, and clients' satisfaction. A systematic search of studies reporting on client-led appointment scheduling of psychological therapy for individual clients was conducted. Full text of forty two peer-reviewed studies was examined and sixteen eligible- studies were identified. Study outcomes included appointment attendance, the impact of therapy on symptoms, and clients' perspectives of the intervention. Results suggest that when clients schedule their own appointments, the majority attend a smaller number of sessions (between one and seven on average) compared with the session numbers recommended by treatment guidelines; non-attendance rates are lower compared to interventions with prescribed numbers of sessions; therapy reduces symptoms; and clients perceive the interventions as useful.

Keywords: client-led appointment scheduling, partial booking, psychological therapy, Method of Levels, attendance, missed appointments.

Highlights:

- High levels of missed appointments and treatment dropouts lead to wasted resources
- There is large variation between clients in the number of sessions required for symptom improvement
- Client-led appointment scheduling can improve attendance and reduce waiting lists

- Client-led appointment scheduling can result in patients attending smaller numbers of sessions at irregular intervals
- Clients attending self-scheduled therapy sessions show significant reduction in symptoms of medium to large effect size
- Clients value choice and control over scheduling their own appointments

1. Introduction

Delivering psychological interventions requires applying various parameters on the frequency, number, and duration of the treatment sessions. These parameters have been determined largely by national guidelines, clinicians, and researchers (Carey, 2005). For example, NICE recommends between 12 and 15 weekly sessions for anxiety (National Institute for Health and Care Excellence [NICE], 2011) and 16 sessions for psychosis (NICE, 2014). The rationale underpinning the particular number or other aspects of sessions is, however, unclear.

Research investigating the role of parameters in therapy often applies an approach, familiar in the development of pharmacological treatments, of a dose-response relationship. The dose of therapy corresponds to the number of sessions, and the response is the improvement in the clients' symptoms. Early studies of psychotherapy found that measurable benefits can be achieved with 50% of clients after eight sessions, 75% of clients after 26 sessions, and 85% after a year of weekly sessions (Howard, Kopta, Krause, & Orlinski, 1986). The dose-response relationship in psychotherapy has been described as a negatively accelerating response curve, where clients experience the greatest effect of therapy within the first eight sessions, and after that, the improvement occurs more slowly with each subsequent session (Howard et al., 1986; Robinson, Delgadillo, & Kellett, 2019). According to this interpretation, every client experiences progressively diminishing gains as the length of the treatment increases (Barkham et al., 2006). When these individual curves of progressively diminishing benefits are aggregated, the resulting averaged curve also shows a negatively accelerating pattern.

Contrary to this, there is evidence that when session-by-session improvement in symptoms is plotted, the resulting patterns are linear, i.e. for a given client each session brings similar benefit (Barkham et al., 1996). From this perspective, the

negatively accelerating response curve shows a pattern of diminishing gains because clients exit treatment after varying numbers of sessions, and different points on the curve represent different groups of people; with end points showing improvement experienced by those people with the slowest response to treatment. It is possible that clients attend appointments until they achieve a 'good enough level' (GEL) of improvement (Barkham et al., 2006; Barkham et al., 1996). The GEL model can be understood as representing responsiveness: the client and therapist regulate the length, focus, or strategies of treatment as a result of the changes achieved. The GEL is different for every client and depends on a variety of factors, such as the nature of the problem, resources of the client, and aspects of the intervention. This is in line with evidence that the optimal dose of psychotherapy varies widely depending on the population, setting, and outcome measure used (Robinson et al., 2019). The majority of clients need a low number of sessions, and a small number of clients require a high number of sessions, whilst some people improve at a medium point (Barkham et al., 2006).

The law of diminishing gains, as applied to dose-response research on psychotherapy, suggests that there is little benefit in offering clients large numbers of sessions because the probability of improvement after session 26 is very low (Howard et al., 1986; Robinson et al., 2019). On the other hand, the GEL model proposes that the optimal number of therapy sessions is different for every person and reflects responsiveness on the part of the client and the therapist (Barkham et al., 2006). Accordingly, a predetermined number of appointments applied to all clients might not be appropriate (Barkham et al., 1996). Indeed, clients often cease attending therapy before the predetermined number of sessions is achieved (Carey, 2005). Such cessation is considered premature from the point of view of services, usually referred to as 'dropout', is associated with missed appointments, and regarded as an inefficient use of resources.

Dropout rates across different therapies and for different diagnoses have been reported to vary from over one in four to one in six clients, irrespective of therapy modality, therapist, or client characteristics (Cooper & Conklin, 2015; Dixon & Linardon, 2019; Gersh et al., 2017). In fact, some studies have estimated that, on average, clients attend between 3.9 and 5.5 sessions; less than the standard number offered (Carey, 2006; Hynan, 1990). Reasons for cessation of therapy are varied and

include situational factors (e.g. changes in family life or work), perceptions of therapists as not warm or competent enough (Hynan, 1990), and poor therapeutic alliance (Anderson, Bautista, & Hope, 2019). However, other studies of dropout rates suggest that a considerable proportion of clients who terminate treatment early do so because of reduction in symptoms (Altmann et al., 2018; Pekarik, 1983), particularly when termination takes place after six or more sessions (Aderka et al., 2011). This is consistent with the argument that therapists offer more sessions than clients expect (Aderka et al., 2011; Owen, Smith, & Rodolfa, 2009; Pekarik & Wierzbicki, 1986). Finally, some clients miss their appointments because of the rigidity of the services, which do not offer them choice of time and date (Marshall et al., 2015).

Whilst many clients stop attending appointments before the standard number of sessions is complete, with many appointments being scheduled but missed, clients in need of treatment are often subject to lengthy waiting times; demonstrating that there is a discrepancy between demand - the need for therapy, and supply – the capacity of services (Beintner & Jacobi, 2018). Similar difficulties with missed appointments and long waiting times are often encountered in physical health settings, some of which have successfully resolved them by adopting patient-centered appointment booking systems (Parmar, Large, Madden, & Das, 2009; Zhao, Yoo, Lavoie, Lavoie, & Simoes, 2017). These often consist of internet-based platforms, where patients can make decisions about their appointments according to their preferences. The positive changes associated with internet-based booking systems include reduced ‘no-show’ rates and waiting times, increased patient satisfaction and service efficiency.

Rationale for the review

Evidence suggests that the optimum ‘dose’ of therapy, quantified as the number of sessions received, is highly variable (Robinson et al., 2019) and the standardised length of treatment might be inappropriate as it fails to take into account differences between rates of improvement of individual clients (Barkham et al., 2006). Yet in clinical practice, clients are typically offered a predetermined and standard number of sessions. A proportion of these sessions is then missed, resulting in waste of resources, which could be allocated to those on the waiting lists. It is unclear what

the rates of missed and cancelled appointments would be if clients were in control of scheduling their therapy sessions.

The objective of the current review was to identify and synthesise findings from studies investigating client-led appointment scheduling where the number, frequency, and duration of therapy sessions were determined by the client. Specifically, this review explored the impact of client-led appointment scheduling on the following clinical outcomes: appointment attendance, change in symptoms, and client satisfaction.

2. Methods

2.1. Data sources and search strategy

The systematic search strategy was performed in accordance with the Preferred Reporting Items and Meta-Analyses (PRISMA) statement guidelines (Moher, Liberati, Tetzlaff, Altman, & Group, 2009). The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42019161151). The search of electronic databases (Web of Science, CINAHL, PsycINFO, Medline) was performed on the title and abstract level and was complemented with handsearching the references of identified studies. Grey literature was not searched. The initial scoping exercise revealed that studies of client-led appointment scheduling were sparse and used varied terminology. Keywords, therefore, were grouped into two main concepts: client choice and psychological therapy. The keywords used within the concept of psychological therapy included both general terms (e.g. ‘psychological intervention’) and specific therapies listed in the NICE guidelines for treatment of mental health problems (NICE, 2011, 2009, 2017, 2011, 2018, 2014, 2013).

Keywords, listed in Table 1 (see Appendix B for exact search strings), were combined with the Boolean operators ‘OR’ and ‘AND’. Truncation, inverted commas, and proximity operators were used to broaden or focus the search.

Table 1: Database search terms used to identify studies related to client-led appointment scheduling

Client choice related words	Psychological therapy related words
patient led	psychological therapy
client led	psychological treatment
service user led	psychotherapy
	mental health practice
patient control	mental health treatment
client control	mental health intervention
service user control	counselling
	cognitive behav* therapy
patient choice	interpersonal therapy
client choice	psychodynamic therapy
service user choice	mindfulness-based cognitive therapy
	eye movement desensitization and reprocessing
partial booking	
self-booking	

Due to the paucity of research on the subject of client-led appointment scheduling, no limits on publication date were set and broad search criteria were employed. The electronic database search revealed 7793 studies (Figure 1) dating from 1917. Seven papers were added through handsearching of references of the 9 papers identified through database search (Table 2). Removal of duplicates resulted in 6132 studies. Following the title and abstract screening, 42 papers were included for full text screening. Twenty six papers were excluded and 16 were retained.

Table 2: List of studies selected via database search and hand searching of references.

Studies identified via database search	Studies identified via reference search
Kenwright & Marks, 2003	Chiesa, 1992
Reid et al., 2005	Carey, 2005
Carey & Mullan, 2007	Carey & Kemp, 2007
Carey & Spratt, 2009	Carey & Mullan, 2008
Carey et al., 2013	Carey et al., 2009
Jenkins, 2017	Houghton et al., 2010
Churchman et al., 2019a	Griffiths et al., 2019b
Churchman, et al., 2019b	
Griffiths et al., 2019a	

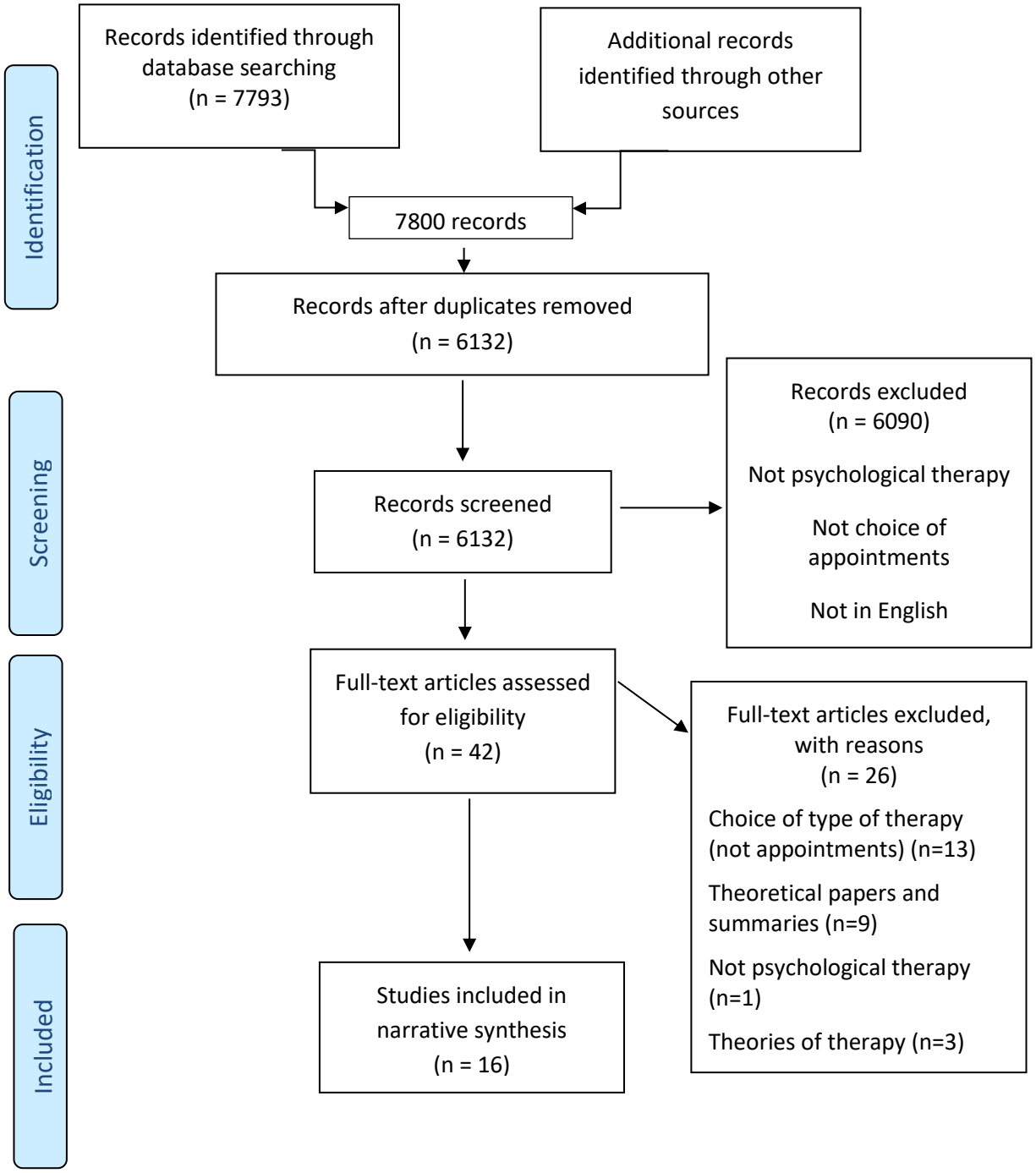

Figure 1: PRISMA flow diagram.

2.2. Eligibility criteria

Inclusion:

- Adults aged 16+. Studies with adult participants were selected because, in a mental health setting, children would be less likely to book their own appointments, especially in cases of family therapy. An exception was made for studies where children were able to book their own appointments.
- Studies employing client-led appointment scheduling in the context of psychological therapy provided to individual clients.
- Quantitative, qualitative, and mixed method designs.

Exclusion:

- Studies where the number or frequency of therapy appointments was predetermined or set by the clinician or researchers.
- Studies of family therapy. These papers were excluded because family therapy is employed in the treatment of children, however it is unlikely that the child would choose the time and frequency of appointments. In addition, as family therapy is provided to a group rather than to an individual, it is not possible for one person to choose when and how many sessions they require.
- Book chapters.
- Studies in languages other than English.

Titles and abstracts were screened against the predetermined inclusion and exclusion criteria. Studies were categorized as excluded or included for full text access.

2.3. Data extraction

Data were extracted into a data extraction sheet (Table 3) in order to provide information about the characteristics of the studies (design, setting, and measures used), participants (number, age, gender), study aim, and the main findings.

2.4. Quality appraisal

The Quality Assessment Tool for Studies with Diverse Designs (QUATSDD; Sirriyeh, Lawton, Gardner, & Armitage, 2012) was used to appraise the quality of the selected studies. Designed for application with research studies of varied methodology, QUATSDD has been shown to have good face validity and inter-rater reliability. Studies were assessed on 14 reporting and methodological quality criteria concerned with theoretical framework, design, data collection and analysis, as well as critical discussion (Table 4). Scores ranged from 0 (criterion not fulfilled at all) to 3 (criterion fulfilled completely). An independent researcher assessed 3 studies (18.75%) of the studies. A high degree of reliability was found between the two raters (intraclass correlation coefficient was 0.93 with a 95% confidence interval from 0.87 to 0.96 ($F(41,41)= 14.75$, $p<.001$); see Appendix C).

2.5. Patient and public involvement

Liaison with a Patient and Public Involvement (PPI) group began in the developmental stages of the review. Specific feedback was sought over the initial protocol to ensure that a PPI perspective informed the review at every stage.

3. Results

3.1. Data synthesis

Since the reviewed studies focused on different research questions it would not have been appropriate to conduct either a meta-analysis or a meta-synthesis. The results of the studies were subject to a narrative synthesis which included a quality appraisal. Data were grouped according to outcome measures. For the purpose of the review, the term ‘client-led scheduling’ is used interchangeably with ‘self-booking’. In cases where appointments were scheduled by the health care provider, they are referred to as ‘service-booked’. Missed appointments are instances where a client booked the appointments but did not attend, without prior cancelling or rescheduling. Cancelled appointments will be considered separately where possible.

Table 3: Description of the 16 research studies reviewed.

Study ID (country)	Research design, setting, duration, therapists N	Measures	Participant N, % male, average age (range)	Aims	Key findings
Chiesa, 1992, UK	Cohort study with a historical comparison group (self-booked first appointments in 1985 and service-booked first appointments in 1979). Outpatient psychotherapy.	Number of referrals for therapy, attended and missed first appointments, number of clients offered therapy, therapy attendance in the first two months.	65 referred in service-booked group. 207 in self-booked group. No data on gender or age.	To investigate the effects of self-booking on first appointments attendance.	Significantly lower rates of missed self-booked (1%) than service-booked appointments (15.3%). No significant difference in the numbers of clients offered psychotherapy or in early dropouts (therapy scheduling was not client-led). Relative to the number referred, fewer self-booked than service-booked clients commenced therapy.
Kenwright & Marks, 2003, UK	Randomized controlled trial. Outpatient cognitive behavioural therapy clinic for anxiety and depression.	Number of referrals, number of attended, missed and cancelled first appointments.	148 referrals, 46.6%. 73 service-booked clients, 75 self-booked clients. Average age: 32.5. No data on age range.	To evaluate the effects of self-booking on first-appointment attendance rates.	Significantly higher rates of attended first appointments in the self-booking system compared with the service-booked system.
Carey, 2005, UK	Pragmatic uncontrolled trial (routine practice at a GP surgery and in outpatient clinics). 18 months 1 clinician Primary and secondary mental health care.	Number of attended and missed appointments, frequency and duration of appointments. Self-rating pre- and post measures of levels of distress. Open -ended feedback from patients.	98, 49%. No data on average age (18-65). 24 returned pre- and post-questionnaires.	To assess feasibility of patient-led treatment schedule.	Median number of sessions attended: 2, range: 1-22. Average session duration 35.5 min (range:13–80). Average cancelled or missed appointments: 1. Wide variation in frequency and duration of sessions. Lower distress following therapy.

Study ID (country)	Research design, setting, duration, therapists N	Measures	Participant N, % male, average age (range)	Aims	Key findings
Reid et al., 2005, UK (North West England)	Pragmatic uncontrolled trial. A trial of a self-booking system for appointments. Psychology service.	Number of attended and missed appointments. The outcome (whether further input was offered).	50, 28 %. Mean age: 37.88 (SD=14.08). Age range not reported.	To investigate whether self-booking system reduces the number of missed first appointments in a psychology service.	The number of missed appointments 2% as compared with reported average 31.7%.
Carey & Kemp, 2007 UK	Pragmatic controlled trial. Hospital outpatient clinic.	Number of attended and missed appointments.	Self-booking group: 164, 36%. Age: 34 (17-63). Service-booked group: 62, 34%. Age: 42 (16-76).	To compare attendance of self-booked and service booked first appointments.	Number of attended first appointments significantly higher in the self-booked compared to service-booked group (87% vs 61%). Number of missed appointments significantly lower in the self-booked, compared with the service-booked group (2% vs 21%). Number of cancellations similar in the self-booked and service-booked group (12% and 18%).
Carey & Mulan, 2007 UK, Scotland	Pragmatic uncontrolled (routine practice in GP surgery). 6 months, 2 clinicians	Number of attended, missed, cancelled appointments, length of sessions, waiting list. DASS21. Open-ended feedback from GPs and clients.	101, 40.6%. Age: 34 (13-81). 25 attended > 1 session.	To trial client-led scheduling of psychological therapy (MOL) in a GP setting.	Median number of appointments attended: 1, range: 1-6. Median missed: 0, range: 0-4. Median cancelled: 0, range 0-5. Average length of sessions: 30 min, range: 10-290. Waiting list reduced to none. DASS scores of those who attended >1 session changed on average from severe to moderate range. Prescription of antidepressants increased at slower rate compared to other areas.
Carey & Mulan, 2008, Scotland (UK)	Refer to Carey & Mulan, 2007	Refer to Carey & Mulan, 2007	Refer to Carey & Mulan, 2007	To investigate whether MOL therapy reduces the symptom level; the difference in the initial	Significant decrease in the symptom level in patients who attended >1 session (large effect size).

Study ID (country)	Research design, setting, duration, therapists N	Measures	Participant N, % male, average age (range)	Aims	Key findings
				symptom level between patients who attended 1 session and patients who attended >1 session; the relationship between the number of sessions attended and initial symptom level.	No relationship between the number of sessions attended and the size of the difference in symptom level. No difference in the initial symptom level between patients who attended 1 session and patients who attended >1 session. No relationship between the number of sessions attended and the initial symptom level.
Carey et al., 2009, UK	Pragmatic uncontrolled trial (routine practice at 2 GP surgeries and 2 outpatient clinics). 12 months 4 clinicians	DASS-21, The Distress Perception Questionnaire, Open-ended questionnaire	N: 120, 31.67%. Age: 38.5 (16-66). 63 returned follow-up questionnaires.	To establish how many sessions patients attend when provided with unlimited number of appointments. To investigate if MOL therapy is useful to patients.	Median number of attended appointments: 2, range 1-15. Significant reduction in symptom level. Significant inverse correlation between time on the waiting list and change in symptom level. No relationship between the number of sessions attended and initial symptom level. Feedback from client- MOL therapy was useful.
Carey & Spratt, 2009, UK	Pragmatic uncontrolled trial (routine practice in GP surgery). 9 months 2 clinicians	DASS-21	N: 167, 40%. Age: 36 (16-87). 55 patients attended > 1 appointment. .	To trial patient-led scheduling of appointments in psychological therapy (MOL).	Waiting list decreased to none. Referral number increased. Mean session duration: 30 min. Median number of appointments attended: 1, range 1-11; median missed: 0, range 0-3. Median cancelled: 0, range: 0-5. Descriptive data: symptom level decreased in those who attended >1 session. Their time 2 score (from the most recent session) similar to the score of those attending only 1 session.

Study ID (country)	Research design, setting, duration, therapists N	Measures	Participant N, % male, average age (range)	Aims	Key findings
Houghton et al., 2010, UK	Cohort study with a historical comparison group. Comparison of attendance of first appointments in self-booking system and service-booked system. NHS psychotherapy service.	Number of attended and missed appointments. Number of clients who did not book their appointments in self-booking system and their diagnosis.	N: 620, 40.3%. 331 referred in service-booked system, 289 in self-booking system. No data on age.	To investigate whether an opt-in letter (self-booking) as a route to a first appointment increases attendance and if it discriminates against any group of clients.	There was a non-significant reduction in the number of missed appointments between the service-booked system (20%) and self-booking system (15%). Significantly fewer self-booking than service-booked patients attended their first appointment. Significantly more patients with anxiety than with other problems did not book their appointments.
Carey, Tai, & Stiles, 2013, (rural) Australia	Benchmarking pragmatic trial (data collection during routine practice in Adult Community Team in remote areas) 2 years 1 clinician	Number of attended, missed and cancelled appointments. ORS SRS	N: 92, 55.43%. Age: 38.1 (18-67). 51 patients attended >1 appointment. 47 had initial ORS score below the clinical cut-off.	To investigate the effectiveness and efficiency of MOL therapy (within a self-booking appointment system).	Mean number of attended appointments 2.9, range: 0-7. Mean cancelled: 0.4, range: 0-3. Mean missed: 1.2 (0-4). Significantly higher level of distress in patients who attended 1 session compared to those who attended > 1 session. Similar effectiveness to other psychological therapies with lower number of attended sessions- higher efficiency (in addition to low number of cancelled and missed appointments).
Jenkins, 2017, UK	Cohort study with historical comparison group. Comparison of self-booked and service-booked appointments. Eating disorder service.	Percentage of missed appointments.	N:1260. No data on gender or age.	To investigate the effectiveness of self-booking system of first appointments in reducing rates of missed appointments.	Significantly fewer patients in the self-booked system (15.1%) compared with the service-booked appointment system (20.4%) missed the first appointment (medium-sized effect).
Churchman et al., 2019a	Single case series in a secondary school setting. 6 months treatment window.	YP –CORE GBO GHQ-12 YES	16, 56% Age: 13.2 (11-15)	To determine feasibility, acceptability and effectiveness of MOL	Recruitment completed within the allocated time. 75% retention. Mean number of sessions attended: 7 (range: 1-18).

Study ID (country)	Research design, setting, duration, therapists N	Measures	Participant N, % male, average age (range)	Aims	Key findings
UK (secondary school in the North West)	1 therapist.	ROC C/SRS		intervention in young people.	5 participants recovered, 7 remained the same. Effect size medium to large.
Churchman et al., 2019b UK	Qualitative interviews with 14 participants of the Churchman et al. (2019b) study.	Interviews. Data subject to thematic analysis.	14, 9% Age: 13.14 (SD: 1.29)	To investigate how young people experienced MOL therapy and being put in charge of booking their appointments.	Choice and control were important to the participants booking appointments and process of therapy. Participants valued feeling listened to and understood, exploring the different perspectives on the problem.
Griffiths et al., 2019a, UK	Feasiblity and acceptability randomized controlled trial. Treatment as usual (TAU) and TAU +MOL therapy;10 month treatment window. 1 therapist. Early Intervention Services.	Recruitment, retention attrition at follow up, acceptability. Number of attended, missed and cancelled appointments. Length of appointments. Reasons to end therapy.	36, 63.9% Age: 30.6 (SD: 10.7)	To investigate acceptability and feasibility of MOL therapy in an early intervention service.	Retention: 97%. Participant feedback indicated the intervention was acceptable. 62% of booked sessions attended, 29.3% cancelled, 8.7% not attended. Mean number of attended sessions: 3, median: 2, range: 0-10; mean cancelled:1.4, median: 0, range: 0-10; mean missed: 0.4, median: 0, range: 0-2. Mean length of therapy sessions: 48 min (SD: 19.3, range: 7–107). Reasons for ending therapy: 18.8% achieved what they needed, 37.5% ran out of time, 43.8% 'other' (work and educational commitments), 0% did not get what they needed.
Griffiths et al., 2019b, UK	Qualitative Interviews with 12 participants of the feasibility RCT (Griffiths et al.,2019a).	Interviews. Data subject to thematic analysis.	12, 58% Age: 33 (19-62)	To explore participants' experience of MOL therapy within client-led appointment scheduling system. To explore the mechanism of change underpinning MOL	Clients found MOL helpful and particularly valued having control over the appointments booking and the process of therapy, being able to explore problems in depth and from different perspectives, speak openly.

Study ID (country)	Research design, setting, duration, therapists N	Measures	Participant N, % male, average age (range)	Aims	Key findings
				therapy in the context of the client's perspective.	

MOL: Method of Levels
DASS: Depression, Anxiety, Stress Scale
ORS: The Outcome Rating Scale
SRS: The Session Rating Scale
PSYCHLOPS: Psychological Outcome Profiles
CORE-OM: Clinical Outcomes in Routine Evaluation
ROC: Reorganisation of Conflict Scale
QPR: Questionnaire about the Process of Recovery
YP-CORE: The Young Person's Clinical Outcomes in Routine Evaluation
GBO: The Goal-Based Outcome Measure
GHQ-12: The General Health Questionnaire-12
YES: The Youth Empowerment Scale
C.SRS: The Child/Session Rating Scale
MOL: Method of Levels
TAU: Treatment as Usual

Table 4: Quality assessment of the reviewed studies.

Note. [a] Percentage = the total score of a study / the full score 42 (14 items x 3 per item). Average %=72.5%

Study ID (Author, year)	Chiesa, 1992	Kenwright & Marks, 2003	Carey, 2005	Reid et al., 2005	Carey& Kemp, 2007	Carey & Mulan, 2007*	Carey & Mulan, 2008*	Carey & Spratt, 2009	Carey et al., 2009	Houghton et al., 2010	Carey, Tai, & Stiles, 2013	Jenkins, 2017	Churchman et al., 2019a	Churchman et al., 2019b	Griffiths et al., 2019a	Griffiths et al., 2019b
Total score	**22**	**32**	**26**	**23**	**24**	**34**	**36**	**28**	**32**	**35**	**37**	**29**	**32**	**30**	**33**	**32**
%*	**53.66**	**78.05**	**63.41**	**54.76**	**57.14**	**80.95**	**85.71**	**66.67**	**76.19**	**83.33**	**88.10**	**69.05**	**76.19**	**71.43**	**78.57**	**76.19**
Explicit theoretical framework	1	3	3	1	1	3	3	3	3	3	3	3	3	3	3	3
Statement of aims/objectives in main body of report	2	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3
Clear description of research setting	3	3	2	2	2	2	2	2	2	2	3	3	2	3	3	3
Evidence of sample size considered in terms of analysis	2	3	2	2	1	2	2	2	2	3	2	2	3	1	2	1
Representative sample of target group of a reasonable size	2	3	2	2	1	3	3	3	3	3	3	3	1	1	2	2

Study ID (Author, year)	Chiesa, 1992	Kenwright & Marks, 2003	Carey, 2005	Reid et al., 2005	Carey& Kemp, 2007	Carey & Mulan, 2007*	Carey & Mulan, 2008*	Carey & Spratt, 2009	Carey et al., 2009	Houghton et al., 2010	Carey, Tai, & Stiles, 2013	Jenkins, 2017	Churchman et al., 2019a	Churchman et al., 2019b	Griffiths et al., 2019a	Griffiths et al., 2019b
Description of procedure for data collection	3	3	1	2	1	3	3	3	2	3	3	3	2	3	2	3
Rationale for choice of data collection tool(s)	1	3	2	2	2	3	3	2	2	3	2	3	3	1	2	2
Detailed recruitment data	2	3	2	3	3	3	3	3	2	3	3	1	3	3	3	3
Statistical assessment of reliability and validity of measurement tool(s) (Quantitative)	1	1	0	0	1	2	2	1	2	2	3	1	2	-	2	-
Fit between stated research question and method of data collection (Quantitative)	3	3	2	2	3	3	3	2	3	2	3	2	3	-	3	-
Fit between stated research question and format and content of data	-	-	-	-	-	-	-	-	-	-	-	-	-	3	-	3

Study ID (Author, year)	Chiesa, 1992	Kenwright & Marks, 2003	Carey, 2005	Reid et al., 2005	Carey& Kemp, 2007	Carey & Mulan, 2007*	Carey & Mulan, 2008*	Carey & Spratt, 2009	Carey et al., 2009	Houghton et al., 2010	Carey, Tai, & Stiles, 2013	Jenkins, 2017	Churchman et al., 2019a	Churchman et al., 2019b	Griffiths et al., 2019a	Griffiths et al., 2019b
collection (Qualitative)																
Fit between research question and method of analysis	2	2	2	2	3	2	3	2	2	3	3	2	3	3	3	3
Good justification for analytic method selected	0	1	2	2	1	3	3	2	3	2	3	1	3	1	3	1
Assessment of reliability of analytic process (Qualitative)	-	-	-	-	-	-	-	-	-	-	-	-	-	3	-	2
Evidence of user involvement in design	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Strengths and limitations critically discussed	0	1	3	0	2	2	3	1	3	3	3	2	1	2	2	2

3.2. Descriptive characteristics of studies, measures, quality, and outcomes

Table 3 contains a summary of the 16 studies included in the review in chronological order. Studies were conducted mostly in the UK (N=15; one study was conducted in Australia), in primary mental health care (N=3), secondary mental health care (N=9), both primary and secondary mental health care (N=2), and in a secondary school (N=2). Sample sizes ranged from 12 to 1260, with 3232 participants in total, aged between 11 and 87 years (nine studies reported an age range). Fourteen studies reported binary gender for participants. Male participants constituted 43.9% of this sample. Three studies provided information regarding the ethnicity of the participants. In these studies, white people accounted for between 85.7% and 92% of the sample. Clients presented with a range of problems including depression, anxiety, relationship problems, anger, addictions, loss, eating disorders, and psychosis. Studies employed a range of designs: pragmatic uncontrolled trials (N=6), randomized clinical trials (RCTs; N=2), cohort studies with historical comparison groups (N=3), qualitative (N=2), pragmatic controlled trial (N=1), benchmarking pragmatic trial (N=1), case series (N=1). The most commonly reported outcome was appointment attendance (N=13), including missed and cancelled appointments. Studies also reported changes in symptoms (N=8), participants' perspectives of the intervention (N=7), retention, and acceptability (including therapeutic alliance; N=3). All studies that invited clients to self-book therapy appointments employed Method of Levels (MOL) therapy - a transdiagnostic, client-led, cognitive treatment (Carey, 2006).

A percentage of the maximum possible quality score was calculated for each study to allow comparison of the quality of the papers. Quality assessment scores ranged from 51% to 88% of the maximum possible score, with an average score of 72.5% (Table 4). Nearly all studies provided sufficient information regarding theoretical framework, aims and objectives, research setting, recruitment of an appropriately sized sample, description of the procedure of data collection, and justification of the data collection tools as well as the method of analysis. However, in many studies, available information on statistical aspects of their data collection tools, and discussion of their limitations, was insufficient. Only one study (Griffiths, Mansell,

Edge, Carey, Peel, & Tai, 2019b) included information about the involvement of service users in the design.

3.3. Impact of client-led appointment scheduling on attendance and duration of sessions

3.3.1. Client-led scheduling of assessment appointments

Six studies reported on first appointment attendance for clients referred for psychological therapy (Carey & Kemp, 2007, Chiesa, 1992; Houghton, Saxon, & Smallwood, 2010; Jenkins, 2017; Kenwright & Marks, 2003; Reid, Leyland, & Gill, 2005). The combined sample size in the five studies was 2576. Four compared attendance in self-booking and service-booked groups and reported significantly lower rates of missed first appointments in the self-booked compared to service-booked group (Carey & Kemp, 2007, Chiesa, 1992; Jenkins, 2017; Kenwright & Marks, 2003). Rates of missed self-booked appointments varied from zero (Kenwright & Marks, 2003) to 15% (Houghton et al., 2010; Jenkins, 2017), whilst rates of missed service-booked appointments ranged from 15% (Chiesa, 1992) to 43% (Kenwright & Marks, 2003). Only one study reported that the decrease in the number of missed appointments in the self-booked group (15%) compared with the service-booked group (20%) was non-significant (Houghton et al., 2010) and one study had no control group but compared the rate of missed self-booked appointments (2%) with an average rate of service-booked sessions (31.7%; Reid et al., 2005). Where the number of cancelled appointments were calculated, no significant difference was found between the allocated and self-booking clients (Chiesa, 1992).

Between 6% (Reid et al., 2005) and 36% (Carey & Kemp, 2007) of clients invited to self-book their first appointments did not reply to the invitation. Houghton and colleagues (2010) reported that the number of clients who attended their first appointment was significantly smaller in the self-booked compared to the service-booked group. In addition, among those who did not self-book their appointments significantly more clients were referred due to anxiety relative to other presenting problems.

Chiesa (1992) found no significant differences between the service-booked and self-booking groups in the number of clients who were offered therapy, the number of clients who took up the offer of therapy, or the rates of dropouts in the first two months of therapy. However, when the number of all referred clients was considered, significantly fewer self-booked clients, compared to service-booked clients, commenced therapy (29% versus 46.2%). This difference was due to some clients in the self-booking group not taking up the offer of scheduling their own first appointments.

Overall, among those people who self-booked their first appointments, attendance rates were high, and the number of missed appointments was significantly lower than when appointments were service-booked (Carey & Kemp, 2007; Chiesa, 1992; Jenkins, 2017; Kenwright & Marks, 2003; Reid et al., 2005). However, a proportion of referred clients invited to self-book their appointments did not proceed and some studies found that clients with anxiety disorders were significantly less likely to self-book their appointments than clients with other presentations and that fewer self-booking clients than service-booked clients commenced therapy (Chiesa, 1992; Houghton et al., 2010).

3.3.2. Client-led scheduling of therapy appointments

Seven studies included in the review investigated the impact self-booking of therapy appointments on on attendance, where the first appointment was usually service-booked (Table 5). The number of appointments attended/missed, as well as appointment frequency and duration, are reported.

3.3.3. Number of attended appointments

Some studies (N=5) (Carey & Mullan, 2007; Carey & Spratt, 2009; Carey, Tai, & Stiles, 2013; Churchman, Mansell, & Tai, 2019a; Griffiths, Mansell, Carey, Edge, Emsley, & Tai, 2019a) reported attendance data for all clients, including those who did not attend any sessions. Others (N=2) (Carey, 2005; Carey, Carey, Mullan, Spratt, & Spratt, 2009) reported data only for those who attended at least one session. Both the median number and the range of attended appointments tended to be higher in the studies of longer duration. In a pragmatic study, Carey (2005) assessed the feasibility of client-led booking of therapy appointments over a period

of 18 months. The number of therapy sessions attended by clients ranged from one to 22. In other pragmatic studies clients attended between one and six sessions during a six-month study (Carey & Mullan, 2007), one and 11 sessions during a nine-month study (Carey & Spratt, 2009) and one and 15 sessions during a 12-month study (Carey et al., 2009). Median numbers of attended appointments varied between one (Carey & Mullan, 2007; Carey & Spratt, 2009) and two (Carey et al., 2009).

A two-year study assessed the number of sessions for clients who attended more than one appointment separately (Carey et al., 2013). The mean number of attended appointments was 3.6, with a median of three, and range between two and 11. High school students who participated in a case series study of MOL in a secondary school attended seven sessions on average and between one and 18 over a six-month period (Churchman et al., 2019a). Clients experiencing a first episode of psychosis using early intervention services who were recruited to a randomised controlled feasibility trial attended three sessions on average (median = 2), and range from zero to 10, during a period of 10 months (Griffiths et al., 2019a). Sixty two percent of the booked appointments were attended in this study.

3.3.4. Number of missed and cancelled appointments

In the pragmatic studies clients, on average, missed between zero (Carey & Mullan, 2007; Carey & Spratt, 2009) and one appointment (Carey et al., 2013), with a range between zero and four (Carey & Mullan, 2007), zero and five (Carey & Spratt, 2009), and zero and six (Carey et al., 2013). Clients experiencing a first episode of psychosis missed between zero and two appointments, with an average of less than one appointment (median: 0) (Griffiths et al., 2019a). Only one study calculated the number of missed therapy appointments as a percentage of all booked sessions (8%) (Griffiths et al., 2019a). Some authors provided data on the weekly average number of appointments booked and missed by all participants: 4.5 booked and 1.2 missed a week (Carey et al., 2013) and 11.3 appointments booked versus 8 attended a week (Carey & Spratt, 2009). One study reported 6.6 appointments attended a week and overall zero appointments missed on average across the duration of the study (Carey & Mullan, 2007).

Across trials, on average, zero appointments were cancelled (Carey & Mullan, 2008; Carey & Spratt, 2009; Carey et al., 2013) with a range between zero and two (Carey et al., 2013), zero and five (Carey & Mullan, 2008; Carey & Spratt, 2009), and zero and ten (Griffiths et al., 2019a).

Table 5. Attendance rates of therapy sessions for self-booked appointments compared to allocated appointments.

		Appointments- median (range)			
Study (duration, N clinicians)	N	Attended	Cancelled	Missed	Duration (minutes)
Carey, 2005 (18 months, 1)	98 (>0)	2 (1-22)	Combined: 1 (-)		35.5 (13-80)
Carey & Mullan, 2007 (6 months, 2)	101 (≥ 0)	1 (1-6)	0 (0-4)	0 (0-5)	30 (10-290)
Carey & Spratt, 2009 (9 months, 2)	167 (≥ 0)	1 (1-11) >0 (136)**	0 (0-5)	0 (0-3)	30 (-)
Carey et al., 2009 (12 months, 4)	120 (> 0)	2 (1-15)		-	
Carey et al., 2013 (2 years, 1)	92 (≥ 0)	2.9* (0-7)	0.4* (0-3)	1.2* (0-4)	-
Griffiths et al., 2019a (10 months, 1)	19 (≥ 0)	2 (0-10)	0 (0-10)	0 (0-2)	48 (7-107)
Churchman et al., 2019a (6 months, 1)	16 (≥ 0)	7.6* (1-18)		-	

Median and range of the attended, cancelled, and missed appointments are provided where available. ' >0' – the sample consisted of only those clients who attended at least one therapy session. '≥ 0'- the sample consisted of all referred (or recruited) clients. '*'- mean. '**' The average of the attended appointments was calculated only for those who attended at least one appointment (N=136), whilst the cancelled and missed appointments were calculated for all referred clients (N=167).

3.3.5. Frequency and duration of sessions

The length of therapy appointments ranged from seven to 107 minutes (Griffiths et al., 2019a), 10 minutes to nearly five hours (Carey & Mullan, 2007), and 13 to 80 minutes (Carey, 2005), with a median of 35 minutes (Carey, 2005), 30 minutes (Carey & Mullan, 2007), and 48 minutes (Griffiths et al., 2019a). Frequency varied widely, from twice weekly to 3-monthly, with most clients not showing a regular pattern (Carey, 2005; Carey & Mullan, 2007; Carey et al., 2013).

Overall, the mean number of attended appointments varied between one and seven (Carey & Mullan, 2007; Churchman et al., 2019a) and the greatest number of appointments attended by individual clients across different studies ranged from six to 22 (Carey, 2005; Carey & Mullan, 2007). On average, participants failed to attend between one and zero appointments and cancelled zero sessions (Carey & Spratt, 2009). The frequency and duration varied, with session lasting, on average, between 35 and 48 minutes, and most clients showing an irregular pattern of attendance (Griffiths et al., 2019a).

3.4. Impact of client-led scheduling of appointments on wellbeing and client satisfaction

3.4.1. Change in symptoms

Three studies reported only descriptive data for distress and symptoms in clients at baseline and after self-booked therapy appointments (Carey, 2005; Carey & Mullan, 2007; Carey & Spratt, 2009). Relative to their baseline scores, the majority of patients who attended self-booked MOL therapy appointments reported less distress (Carey, 2005) and a reduction in symptoms of depression, stress, and anxiety (Carey & Spratt, 2009) from severe to moderate (Carey & Mullan, 2007). Statistical analyses conducted in other studies were in line with these findings, revealing significant reductions in symptoms (Carey et al., 2009) of medium to large effect size (Carey & Mullan, 2008; Churchman et al., 2019a) and a reliable and clinically significant increase in wellbeing (Carey et al., 2013).

The findings regarding the relationship between the number of sessions attended and the level of symptoms at baseline were mixed. In two studies, the number of attended sessions was not associated with the baseline symptom level (Carey et al., 2009; Carey & Mullan, 2008), or with the size of the symptom change (Carey & Mullan, 2008). In another study (Carey et al., 2013), clients who attended one session reported significantly higher levels of distress at baseline compared to those who attended more than one session. Furthermore, Carey and Spratt (2009) provided descriptive data indicating that the symptoms of depression, anxiety, and stress from the last session of those who attended more than one therapy appointment were lower than their scores from the first session, and similar to the scores for those clients attending only one session. This could indicate that people who attended only

one session had lower levels of symptoms at baseline. One study found that the more time clients spent on the waiting list, the less symptom reduction they achieved during therapy (Carey et al., 2009).

One study compared, by benchmarking, the effectiveness and efficiency of MOL delivered in the context of self-booked appointments to other therapies reported in literature (e.g. Cognitive-Behavioural Therapy, psychodynamic therapy, Cognitive Analytic Therapy) (Carey et al., 2013). An "efficiency ratio" was developed for this study to enable the benchmarking to occur. Method of Levels delivered in self-booked appointments was as effective as several other therapies and, when assessed quantitatively with the efficiency ratio, more efficient, as indicated by a similar effect size achieved in fewer sessions, in addition to fewer missed and cancelled appointments (Carey et al., 2013).

Overall, for both descriptive data and also data that were statistically analyzed, results indicated that when clients chose the number and frequency of their therapy appointments they showed improvement in symptoms, in some instances of medium to large effects size (Carey & Mullan, 2008; Churchman et al., 2019a). Benchmarking comparisons of the results of a pragmatic study of MOL in a client-led appointment system with therapy effect sizes reported in the literature suggest that MOL could be more efficient than several other therapies (Carey et al., 2013). There are no clear relationships between symptom level at baseline or symptom change and the number of therapy sessions attended (Carey et al., 2009; Carey & Mullan, 2008).

3.4.2. Clients' perspective of therapy they schedule themselves

Two studies explored in depth clients' perspective on MOL therapy delivered within client-led appointment scheduling. The themes identified in the interviews included the importance of being able to book the sessions when the client needed them (Churchman, Mansell, Al-Nufoury, & Tai, 2019b; Griffiths et al., 2019b). For instance, the theme 'I was in control' comprised of 'I could choose how to book the appointments' (Griffiths et al., 2019b) and the theme 'therapy style' included 'self-booking sessions' (Churchman et al., 2019b). These findings suggest that choice and control were important to the participants.

In addition to in-depth interviews, simple feedback obtained from participants through questionnaires (four studies) revealed that clients found MOL therapy delivered through self-booked appointments helpful (Carey, 2005; Carey et al., 2009), they valued the flexibility of the service, and the quick access to therapy sessions (Carey & Mullan, 2007).

Retention in a case series study and a feasibility and acceptability RCT was 75% and 97%, respectively (Churchman et al., 2019a; Griffiths et al., 2019a). Mean scores on the measures of therapeutic alliance indicated good therapeutic relationships (Churchman et al., 2019a; Griffiths et al., 2019a) and there was no difference in therapeutic alliance indicators between clients who attended one session and those who attended more than one session (Carey et al., 2013). When asked about reasons for ending the therapy, 18.8% of participants in an RCT (Griffiths et al., 2019a) reported that they achieved what they needed; 37.5% reported that they ran out of time, 43.8% gave 'other' reasons (work and educational commitments), and no clients reported not receiving what they needed.

Finally, GPs involved in one of the pragmatic trials of MOL delivered in a client-led appointment scheduling were very satisfied with the results achieved, as well as the easy access to the service with no time delays (Carey & Mullan, 2007).

Overall, clients valued choice, control, and easy access to therapy sessions and found the intervention helpful (Churchman et al., 2019b). Clients reported other commitments and lack of time as reasons that interfered with booking therapy sessions (Griffiths et al., 2019b).

3.5. Other findings

Two studies found that introduction of a client-led appointment schedule reduced the waiting list to none within a few months whilst referral numbers increased (Carey & Mullan, 2007; Carey & Spratt, 2009). Carey and Mullan (2007) encouraged the GPs in the practice where their pragmatic study was taking place to consider psychological therapy before medication and found that the prescription rates of antidepressants increased at a slower rate (by 11%) compared to other areas in the district (17%).

4. Discussion

4.1. Main findings.

This review explored clinical outcomes, including appointment attendance, change in symptoms, and client satisfaction, when client-led appointment scheduling is employed in psychological therapy. Data on the number, frequency, and duration of therapy sessions were summarised, including attended, missed, and cancelled appointments. The review also synthesised findings regarding the change in symptoms and clients' perspective on the self-booking system.

The majority of studies investigating the effects of client-led scheduling of therapy appointments were pragmatic and uncontrolled. Some of them included data only for those clients who attended at least one appointment, which could have reduced the rates of non-attendance.Participants in the studies valued choice and control over booking therapy sessions (Churchman et al., 2019b; Griffiths et al., 2019b). In client-led scheduling, people tended to book a relatively small number of sessions (between 1-7) and the number booked varied (Carey, 2005; Carey & Mulan, 2007; Churchman et al., 2019a). This is consistent with the reports that clients attend, on average, fewer sessions than the standard number offered (between 3.9 and 5.5) (Carey, 2006; Hynan, 1990). The variation in the number of self-booked appointments, accompanied by positive changes in psychological wellbeing are in line with the findings that the dose of psychotherapy, expressed as the number of sessions needed to achieve an improvement in symptoms, is different for every client (Robinson et al., 2019). There was no clear relationship between the number of sessions attended, and either the symptom level at baseline or symptom change during therapy. It is possible that that clients booked therapy sessions until they achieved a level of improvement that they deemed sufficient, as proposed by the GEL model (Barkham et al., 1996; Barkham et al., 2006). Many clients seemed to achieve a satisfactory level of change in just a few sessions whereas some needed many more appointments.

The results of the studies investigating self-booking of first appointments strongly indicated that client-led appointment scheduling reduces the number of missed sessions (Chiesa, 1992; Kenwright & Marks, 2003; Jenkins, 2017; Reid et al., 2005). This finding is consistent with reports that clients missed appointments because they

were not offered a choice of time and date (Marshall et al., 2015). It also provides further support to the evidence from medical settings which indicates that putting patients in charge of scheduling their appointments reduces 'no-show' rates and waiting times, and increases patient satisfaction and service efficiency (Parmar et al., 2009; Zhao et al., 2017). On the other hand, leaving clients in charge of scheduling their first appointments could be associated with a disproportional lack of uptake in those experiencing anxiety (Houghton et al., 2010) and with smaller numbers of clients commencing therapy (Chiesa, 1992).

The conclusions regarding the number of missed appointments are less clear in studies investigating attendance of self-booked therapy sessions. The majority of the reviewed studies reported missed and cancelled appointments as an average number. It is difficult to compare these data with the existing literature due to the differences in definitions and measurements. Some studies in the literature use the terms 'non-attendance' interchangeably with 'dropout' (Marshal et al., 2015), whilst many others define 'dropout' as the number of clients who terminate therapy 'prematurely', i.e. before a predefined number of sessions has been completed or a clinically significant change has been achieved (Swift & Greenberg, 2014). This definition would not apply in client-led appointment scheduling, which does not set a predetermined number of sessions, or an external criterion for completion of therapy. Importantly, whether the termination of therapy is 'premature' is defined by the therapist or the service and not by the client.

Overall, the average numbers of missed therapy appointments in the reviewed studies were low (Carey & Spratt, 2009; Carey et al., 2013), although there was some variation between studies. A reduction in missed appointments would benefit services in the current context of limited resources. Some evidence reviewed here suggests that client-led appointment scheduling reduces waiting lists (Carey & Mulan, 2007; Carey & Spratt, 2009), thus potentially bridging the gap between the capacity of the services and the need for treatment (Beintner & Jacobi, 2018). This could be particularly important in the light of the finding that the more time clients spent on the waiting list, the less symptom reduction they achieved during therapy (Carey et al., 2009).

In every study included in this review of client-led scheduling of therapy appointments, the psychological therapy delivered was MOL. Overall, the evidence indicates that when clients choose the number and frequency of their own therapy appointments, they experience improvement in symptoms of medium to large effect size (Carey & Mulan, 2008; Carey et al., 2013; Churchman et al., 2019) and one study showed that MOL therapy was equally effective and more efficient than other therapies, when benchmarked against the existing literature (Carey et al., 2013).

4.2. Study limitations

The validity of the findings of this review has several limitations. The number of studies included is low and seven out of sixteen were identified by hand searching of the references. The small number of relevant publications relative to the number of results could be partly due to poor definition of the topic, with different authors using a wide variety of terms. In addition, the client-led approach might be discussed in studies implicitly, and thus can be difficult to capture with keywords. It is possible that some papers were missedThe pragmatic nature of the majority of the studies is a strength as it increases the generalisability of the findings. On the other hand, all the studies investigating client-led scheduling of therapy appointments employed MOL therapy and were uncontrolled. It is not possible, therefore, to conclude whether the improvement in symptoms, and suggested greater efficiency of MOL compared with other therapies, are due to the greater control over access to therapy, or the nature of the therapeutic approach employed. Finally, conclusions pertaining to the long-term effect of therapy delivered in the client-led system are limited due to the absence of traditional follow up assessments. Since clients can book more sessions at any time, in a naturalistic setting of self-booking therapy scheduling the concept of follow up is not directly applicable.

The homogeneity of the participants could also reduce the generalisability of the findings. Only four studies reported data on the ethnicity of their sample, which consisted mainly of Caucasians. All studies except one were conducted in the UK. These limitations might affect the degree to which the findings can be extended to other countries with different health systems and different cultures.

4.3. Research implications

Future studies should include comparison groups of the client-led and service-booked therapy appointment system. Randomised allocation of participants and greater ethnic diversity would also increase the internal validity of the findings.

more varied methodology, including other therapeutic approaches as comparators, would increase the internal validity of the studies and enhance the overall strength of the evidence (Barnish & Turner, 2017).

As most studies investigating appointment attendance provide data on dropout, rather than rates of missed appointments alone, it is difficult to directly compare the results of the current review with the literature. 'No shows' do not always equate to termination of therapy. Accordingly, it would be beneficial for future research to provide data separately on instances were clients failed to attend scheduled appointments, both as an average rate and a percentage of all booked appointments.

Finally, it might useful to investigate further whether clients with certain diagnoses are less likely to schedule their own first appointments than other clients, and whether this difficulty is present only at scheduling the first appointment or persists in scheduling subsequent therapy appointments.

4.4. Clinical implications

The findings of the current review provide insights into several aspects of client-led appointment scheduling system. It appears that self-booking of first appointments considerably reduces the number of missed assessments, and that the average rates of failed attendance, as well as cancelling of therapy sessions, are low. This finding is important in the light of financial constraints currently experienced by mental health services, and the gap between the provision and demand for psychological services. Reduction of the waiting list could be of particular importance in this context.

The review provides evidence that therapy provided in the context of client-led appointment scheduling system is beneficial to clients, and in one study has been shown to be potentially more efficient than other types of available therapies. The

findings suggest that clients appreciate the flexibility of the self-booking system and the easy access to therapy.

4.5. Conclusions

The current review highlighted some potentially beneficial aspects of client-led scheduling of appointments, including the possibility of reduced rates of non-attendance, a favourable response of the clients and referring clinicians, and the reduction of waiting lists. The results indicate that when given the choice, the majority of clients booked a small number of therapy sessions, they attended their appointments at varying intervals, and rarely missed or cancelled their sessions.

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Paper 2: A case series of Method of Levels (MOL) therapy for people experiencing psychosis.

This paper has been prepared in accordance with the author guidelines of Psychology and Psychotherapy. Theory, Research and Practice (Appendix D)

A case series of Method of Levels, a client-led therapy, for people experiencing psychosis.

Short title: Method of Levels therapy in psychosis.

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Abstract

Background and Aims. This study aimed to examine the potential effectiveness of a client-led, transdiagnostic, cognitive therapy regarding general wellbeing and symptoms of psychosis in people using secondary mental health services. **Method.** A single case study of Method of Levels therapy with six participants was conducted. An A-B design with follow up was employed, with the Outcome Rating Scale as a primary outcome measure and two secondary outcome questionnaires (the Community Assessment of Psychic Experiences and the Reorganisation of Conflict Scale). Data were collected at baseline, after completion of therapy (three months), and at one month follow up. Clients chose the number of therapy sessions they attended, as well as each session's content. **Results.** Clients attended eight sessions on average (range: 2-11). Analysis of reliable and clinically significant change indicated that five out of six participants improved and four recovered. There was little evidence of change in the measure of psychotic symptoms. **Conclusions.** The findings of this single case study suggest that people experiencing psychosis respond well to a client-led, transdiagnostic therapy. Further studies with larger samples and control conditions are warranted.

Keywords: Method of Levels therapy, psychosis, perceptual control theory, client-led scheduling

1. Introduction

Psychosis is an umbrella term used to describe experiences associated with a range of mental health diagnoses, including schizophrenia. Psychosis is characterised by unusual experiences involving hearing, seeing, smelling, feeling and tasting things that others do not, as well as apathy and cognitive problems (Kirkpatrick, Buchanan, Ross, & Carpenter, 2001). Standard interventions consist of neuroleptic medications (National Institute for Health and Care Excellence [NICE], 2014). For many people, however, neuroleptic drugs fail to sufficiently reduce their symptoms (Carpenter & Koenig, 2008) or result in intolerable side effects, such as weight gain and extrapyramidal symptoms (Lieberman et al., 2005). Cognitive Behaviour Therapy (CBT), the recommended psychological therapy for psychosis (NICE 2014), aims to reduce distress and improve quality of life by changing client's cognitive, emotional, and behavioural responses to their experiences (Morrison & Barratt, 2010). The

therapy has been shown to be effective for symptoms of psychosis, such as hallucinations (van der Gaag, Valmaggia, & Smit, 2014) and harmful compliance with command voices (Birchwood et al., 2014). Rigorous meta-analyses, however, show that CBT for psychosis has a modest effect size (Jauhar, Laws, & McKenna, 2019; Jauhar et al., 2014). Other evidence suggests that CBT fails to reduce symptoms in those who do not respond to medication (Morrison et al., 2018), and that comorbid problems such as substance misuse require additional therapeutic approaches (Barrowclough et al., 2010). Some patients describe CBT as difficult to engage with, as well as emotionally and cognitively challenging (Kilbride et al., 2013; Wood, Burke, & Morrison, 2015).

Alternative therapeutic approaches are needed to increase the choice of treatment available to patients. Some of the recent developments include metacognitive and mentalization-based therapies, which encourage people to reflect on mental states, both their own and those of others, and to regulate their relationship with their mental events (Hamm & Leonhardt, 2015; Knauss, Ridenour, & Hamm; 2018; Lysaker, Gagen, Moritz & Schweitzer, 2018). Explorative self-reflection and experiental processing are emphasised by the cognitive therapy utilized in the Staying Well after Psychosis approach (Gumley & Schwannauer, 2006). Method of Levels (MOL) is a transdiagnostic psychological therapy which shares some aspects of these approaches, such as the focus on the client' present experience and process of thinking, as well increasing their understanding of themselves rather than learning new skills or ways of behaving.

based on Perceptual Control Theory (PCT) (Tai, 2009). PCT provides an explanation of human behaviour based on the phenomenon of control (Powers, 2008). It proposes that people, and all other living entities, aim to control their experiences, i.e. to make the way they perceive the environment conform to their goals, or reference standards (Carey et al., 2017). Goals have been defined as "internal representations of desired states, where states are broadly construed as outcomes, events or processes" (Austin & Vancouver, 1996) and are organised hierarchically. Integral to this hierarchical organisation is the notion that lower-level procedural goals (e.g. to try one's best at work; to have close relationships) are linked to more abstract and general higher-level goals, akin to personal values or principles (e.g. to have a successful career; to feel loved). A current experience is

compared to a desired state and any discrepancy is then minimised through random changes being made at various levels of the control system (Powers, 2008). Psychological distress occurs when incompatibility between goals exists within the control system. Conflict between two or more goals disrupts the control process and chronic loss of control can lead to mental health issues.

MOL is a direct therapeutic application of PCT, in which therapeutic change is understood as a process of resolving chronic conflict, referred to as reorganisation (Tai, 2009). For reorganisation to happen, awareness must be directed to where the source of the conflict is located within the control system (Powers, 2008). Increased awareness promotes the generation of new solutions and perspectives on a problem, allowing the individual to resolve their conflicting goals and restore control. An MOL therapist begins the session by asking the client what they want to talk about and maintains an open and curious attitude throughout the therapy, with two goals in mind. The first goal is to encourage the client to talk freely about the problem, thus holding it in awareness (Carey, 2006; Carey, Mansell, & Tai, 2015). The second goal is to draw the client's attention to the 'disruptions' – fleeting changes in the flow of speech or facial expressions, which might reflect background thoughts. These momentary changes in awareness, if brought to the forefront of attention, could allow the client to 'move up' the levels of the control system to the source of the conflict. According to PCT, exploration of the problem and its source facilitates reorganisation through considering different aspects of the problem and developing new perspectives. In turn, the resolution of the conflict reduces distress. Since reorganisation is idiosyncratic, the process of conflict resolution and the number of sessions required to restore control is different for every individual (Carey et al., 2017). Accordingly, there is no prescribed number of appointments that clients should attend. Previous studies have shown that clients value being able to book their therapy sessions when they need them and that the average number of sessions booked tends to be smaller than the standard number of CBT sessions recommended by NICE (Carey & Mullan, 2007; Carey, Tai, & Stiles, 2013; Griffiths et al., 2019a).

PCT offers a framework for understanding the origins and maintenance of psychotic experiences and associated distress (Tai, 2016). Within this framework symptoms of psychosis are manifestations of conflict and subsequent reduced control. A diagnosis of a psychotic disorder is often preceded by traumatic life events, characterised by

powerlessness and an inability to escape (Read, van Os, Morrison, & Ross, 2005). Internal dilemmas (e.g. wanting to be close to someone but also wanting to be safe) can lead to psychotic experiences such as paranoia (Tai, 2009) and auditory hallucinations can be experienced as interfering with personal goals (Varese, Mansell, & Tai, 2017). In addition, existing conflict might be exacerbated by unhelpful attempts at controlling the symptoms (e.g. thought suppression, social withdrawal, or substance use) (Morrison & Wells, 2000).

MOL targets the mechanism proposed to underpin all types of psychological distress and, therefore, is suitable for individuals with comorbid problems. It gives patients greater control over the scheduling of sessions, reducing the problem of missed appointments. It also allows the person to focus on their idiosyncratic problem, making it more relevant to that individual. Evidence from pragmatic trials in primary and secondary mental health settings shows that MOL reduces the symptoms and distress in clients with diagnoses ranging from depression and anxiety to eating disorders and substance misuse (Carey, Carey, Mullan, Spratt, & Spratt, 2009; Carey & Mullan, 2008; Carey et al., 2013). The therapy has also been shown to be helpful for young people, in a case series conducted in a secondary school (Churchman, Mansell, & Tai, 2019a).

Preliminary data from single case work on using MOL with people experiencing psychosis (Tai, 2009), as well as from a feasibility and acceptability randomised controlled trial conducted in early intervention services (Griffiths et al., 2019a) suggest that MOL is feasible and acceptable. However, there are no current published data providing supporting evidence for MOL as a treatment for individuals who have experienced more than one episode of psychosis receiving support from secondary mental health services. In line with the hierarchy of levels in evidence-based medicine, a single case study would provide preliminary evidence regarding the effectiveness of MOL in a secondary mental health setting; in particular, whether a short-term, flexible cognitive approach is useful to individuals experiencing chronic psychosis. The aim of this study was to acquire descriptive data on how individuals experiencing non-affective psychosis respond to MOL in order to assess the potential effects of MOL on general functioning, symptoms of psychosis and distress.

2. Method

2.1. Study design

A single case study was conducted. The study employed an A-B design with follow up (A = no-treatment baseline; B = MOL intervention) (Franklin, Allison, & Gorman, 1997). The estimate of the number of participants needed was based on the existing literature (Abu-Zidan, Abbas, & Hefny, 2012; Searson, Mansell, Lowens, & Tai, 2012; Taylor et al., 2019). This research study was registered on a database of clinical studies (ref: NCT04038112).

2.1.1. Measures

Outcome Rating Scale

The primary outcome was measured with the Outcome Rating Scale (ORS) (Miller, Duncan, Brown, Sparks, & Claud, 2003) (Appendix E), a visual analogue scale assessing changes in the past week in the individual, relational, and social domains of the participant's life. The total score ranges from zero to 40, with scores below 25 indicating clinically severe levels of distress. The scale has a high internal consistency, with alpha coefficient ranging from 0.71 to 0.96, and a concurrent criterion validity of 0.70 or above, when cross-validated with the Patient Health Questionnaire, the Outcome Questionnaire-45, the Depression, Anxiety, Stress Scale-21, and the Quality of Life Scale (Harris, Murphy, & Rakes, 2019).

Secondary outcome measures

Community Assessment of Psychic Experiences

Since the current study aimed to investigate the experience of, and response to MOL therapy in psychosis, a measure of psychotic symptoms was also used. Community Assessment of Psychic Experiences Scale (CAPE; Appendix F) is a 42-item self-report measure of the frequency of psychotic experiences and associated distress. It consists of three domains: positive (20 items), negative (14 items), and depressive (8 items), each measured on 4-point Likert scales (Boonstra, Wunderink, Sytema, & Wiersma, 2009). The weighted score (total score divided by the items completed) in all subscales, and in the total scale, ranges from 1 to 4 for both frequency and distress. Items related to the distress dimension can be omitted if a given experience

does not cause distress, and thus only the scores of the answered questions are counted. CAPE has a good internal reliability (meta-analytic mean of 0.91), satisfactory factorial validity (Mark & Toulopoulou, 2016) and good discriminative validity (standardized effect sizes of 0.6–0.8) (Konings, Bak, Hanssen, van Os, & Krabbendam, 2006). Although initially developed to detect subclinical psychotic-like experiences in the general population (Konings et al., 2006), CAPE has been employed in clinical studies (Boonstra et al., 2009; Cevik et al., 2019; Kother, Lincoln, & Moritz, 2018; Mossaheb et al., 2012).

The Reorganisation of Conflict Scale (ROC)

ROC (Bird, 2013) (Appendix G) is a 22-item self-report measure of elements of conflict reorganisation, the mechanisms of change proposed by PCT and promoted by MOL therapy. ROC items correspond to the elements of resolving and overcoming psychological problems, such as facing the difficulties, increased understanding of the problem, and perceiving it in a different way (e.g. 'When I consider a problem, I later become aware that I hadn't thought about it in that way before') (Higginson & Mansell, 2008). Each item is scored on a scale of 0 ("I don't believe this at all") to 100 ("I believe this completely"). The study used the short, 11-item version of the ROC, which showed good reliability (Cronbach's alpha 0.83) (Bird, 2013) whilst reducing the questionnaire burden on the participants. Total score ranges from zero to 1100.

The Session Rating Scale (SRS) (Duncan & Miller, 2003) (Appendix H) is a visual analogue measure of the quality of therapeutic alliance, consisting of 4 aspects: respect and understanding, relevance of goals and topics, client-practitioner fit, and overall alliance. It has been demonstrated to have good validity and reliability (Cronbach's alpha 0.93) (Campbell & Hemsley, 2009). The score ranges from 0 to 40, with scores below 36 (or below 9 on one of the subscales) indicating a potential difficulty in the therapeutic alliance.

The MOL Session Evaluation Form Revised (Carey & Tai, 2012) consists of eight statements reflecting the main aspects of MOL therapy (e.g. 'To what extend did the therapist question rather than assume?', 'To what extent did the therapist facilitate the client's sustained focus in one or more areas?'). Scores range from 0 to 10 on

each item (0 to 80 overall) and provide an indication of treatment integrity and adherence.

2.1.2. Participants

Seven participants were recruited from Community Mental Health Teams (CMHTs) and Recovery Teams in the National Health Service (NHS) in North West England. One participant withdrew after one session of therapy. The final sample consisted of 6 individuals (mean age 44.5, range 29-56, 5 males) (Table 6). Participants had to be registered with a secondary mental health team, and either meet ICD-10 criteria for schizophrenia, schizoaffective disorder or delusional disorder, or meet entry criteria for Early Intervention for Psychosis service. Individuals were unable to take part in the study if they had a moderate to severe learning disability, an organic basis to their symptoms, lacked capacity to consent to participating in research, were not fluent in English, were inpatients, had a primary diagnosis of a drug or alcohol dependency, or were receiving concurrent psychological therapy.

2.1.3. Intervention

Method of Levels therapy was offered up to once a week for up to three months. The researcher explained to the participants that, within the study parameters and the researcher's capacity, they could choose the number, frequency, and duration of therapy sessions. Participants could book the appointments by e-mail or phone or arrange the next session at the end of the current appointment. Each session began with the researcher asking the participant to choose what they wanted to talk about. Appointments were available within the business hours in the clinics where the participants were recruited.

Therapy was delivered by the first author (JN), who received weekly training and supervision from the last author (ST). The written consent form included optional permission for the therapy sessions to be audio recorded (Appendix I). 10% of the sessions were evaluated by the third author (ST), an experienced MOL practitioner, using the MOL Session Evaluation Form Revised (Carey & Tai, 2012). Risk was managed in line with policies and procedures of the University of Manchester and the mental health services where participants were recruited (Appendix J). There were no significant safety concerns during the study.

Table 6: Summary of participant demographic and attendance information

Participant ID	Age	Sex	Ethnicity	Employment Status	Education	Number of sessions attended
Participant 1	56	M	White British	Unable to work due to disability	Secondary school	11
Participant 2	48	M	White British	Part-time	University degree	4
Participant 3	48	F	White British	Unable to work due to disability	GCSEs	2
Participant 4	29	M	White British	Unemployed	University degree	7
Participant 5	52	M	White British	Unable to work due to disability	GCSEs	10
Participant 6	34	M	White British	Unable to work due to disability	GCSEs	9

Education: highest level attained.

2.2. Procedure

The study received ethical approval from the North West Greater Manchester East NHS Research Ethics Committee (ref: 19/NW/0292) (Appendix K) and from the NHS Trust R&D departments. Potential participants were identified by clinicians in the Community Mental Health Teams and Recovery Teams and asked to review a participant information sheet (Appendix L). Following an initial screening appointment, the researcher invited the participants to give written consent to taking part in the study and to complete a demographic questionnaire (Appendix M). The CAPE, ROC, and ORS were completed in two weekly face-to-face meetings of approximately 30 minutes duration with the researcher attending the participants' usual CMHT or Recovery Team base. The participants were then offered three months to access MOL therapy. It was explained to them that the researcher would offer weekly therapy sessions during business hours in their usual CMHT base, that they could decide how many sessions of therapy they wanted to attend, and that they

could book them at the end of the session, or by telephoning, texting, or e-mailing the researcher. All participants chose to arrange the appointments at the end of the therapy session. Therapy sessions were audio-recorded (with participant's consent) for the purpose of supervision and monitoring adherence.

The ORS was completed at the beginning of each session of therapy and the SRS was completed at the end of each therapy session. The completion of each of these measures took approximately two minutes. The ORS, CAPE, and ROC were completed again one week after completion of therapy and after another four weeks (follow-up). As there was no set number of sessions that participants were asked to attend, the last session could not be clearly defined. Accordingly, the post-therapy measures were taken a week after the participant's last session, at the point when either participants informed the researcher that they did not wish to attend more sessions, or the treatment window was closed. Participants were reimbursed for their time when completing baseline, post-therapy, and follow-up measures. The researcher liaised with the clinicians involved in the participants' care to inform them about the progress of therapy and followed the policies of the Trusts regarding risk and recording and sharing of clinical notes.

2.3. Analysis

There are a variety of methods of analysis of single case studies data (Lobo, Moeyaert, Baraldi Cunha & Babik, 2017). Visual analysis of the graphical representation of the data is traditionally performed to observe the level, trend and stability of the data in each phase, as well as immediacy effect and overlap of data between the phases (Morley, 1989). Quantitative analysis of the data provides further information on the magnitude of the intervention effects (Horner, Swaminathan, Sugai & Smolkowski, 2012). Outcomes of the intervention were assessed with a two-fold criterion of clinically significant and statistically reliable change (Jacobson & Truax, 1991). This criterion allows both statistically and clinically meaningful examination of the intervention effects in every participant individually and can be more appropriate to small samples (Busch et al., 2011; Zahra & Hedge, 2010). The analysis of clinical significance was based on treatment completers only.

The change in participant's scores is clinically significant if the pre-treatment score is in the range of a clinical group and the post-treatment score falls in the range of a

non-clinical population according to a pre-calculated 'cut-off' point. The change between post-treatment and pre-treatment score on a given measure is statistically reliable when it is unlikely to have occurred by chance. Participants can be described as 'improved' if their score moves in the direction of fewer symptoms or lower distress, and 'deteriorated' if their score moves in the direction of increased symptoms or distress. Participants whose scores do not show a reliable change in either direction can be described as 'not changed'. The effects of MOL therapy on participants' wellbeing and symptoms in the current study was measured by calculating clinically significant and statistically reliable change from the ORS and CAPE scores.

The reliable change index for the ORS adopted for this study was 5 and the clinical cut-off value was 25 (Miller & Duncan, 2004). As there are no equivalent values reported in the literature for CAPE, the reliable change and clinical cut-off values were calculated according to criterion c and the formula described by Jacobson and Truax (1991): $RC=(x_2-x_1)/S_{diff}$, where x_1 represents participant's pre-treatment score, x_2 represents participant's post-treatment score, and S_{diff} represents standard error of the difference between the two test scores. The calculations were based on the scores of clinical and non-clinical populations published by Kother and colleagues (2018), for symptom frequency in the positive (healthy: mean=1.3, SD=0.14; patients with schizophrenia: mean=1.87, SD=0.48)negative (healthy: mean=1.80, SD=0.41, patients with schizophrenia: mean=2.25, SD=0.57), and depressive (healthy:1.69, SD=0.32; patients with schizophrenia: mean=2.36, SD=0.62) dimensions. The calculation of RC involved the standard deviation of the published sample and CAPE reliability described by Kother and colleagues (2018) and Mark and Toulopoulou (2016). Normative data were not available for the distress component of the scale.

3. Results

Six participants completed the post-therapy and follow-up measures. For three participants, the follow up measures were completed remotely due to the COVID-19 pandemic (Health Research Authority [HRA], 2020).

The average number of attended sessions for participants who completed the study was 7.14 (median: 8), range: 2-11. Out of 49 sessions booked, 3 (6%) were cancelled and rescheduled and 3 (6%) were missed. 10% of sessions were rated by the third author (ST) using the MOL Session Evaluation Form Revised (Carey & Tai, 2013). Average score was 5.5 out of 10 (mean total score: 44.25 out of 80). The average SRS score was 37.94 out of 40, indicating that there were no difficulties in therapeutic relationship (see Figure S5 for supplementary data, Appendix O).

Participants' ORS scores during baseline and therapy, and at follow up are shown in Figure 2. The ORS scores for participants 1, 3, 5, and 6 were improving during baseline. The ORS score of participant 2 and 4 were deteriorating. Following the introduction of MOL therapy, the ORS scores of participant 1, 5, and 6 showed a temporary deterioration. Participant 3, 5, and 6 experienced another temporary deterioration at the end of MOL therapy. The scores of participants 1, 3, and 6 showed variability during therapy, whilst participant 2 and 3 improved significantly within a small number of sessions (four and two, respectively).

Participant 7 dropped out of the study after the first session of MOL therapy. ORS scores from the first therapy session were included in baseline because the measure was complete at the beginning of the session. The average of the three baselines was used to compute the reliable change (Table 7) One participant's baseline score (participant 3) was above the clinical cut-off score of 25 and the scores of the remaining 5 participants were below the cut-off score.

At post-therapy two participants achieved a reliable and clinically significant change.. The post-therapy scores of the remaining four participants were similar to their baseline scores. At 1 month follow up the ORS scores of four participants fell in the category of 'recovered' (improved and crossed the clinical cut-off score) and one participant, whose baseline score was above the clinical cut-off criterion, maintained the reliable change (improved). One participant showed no change.

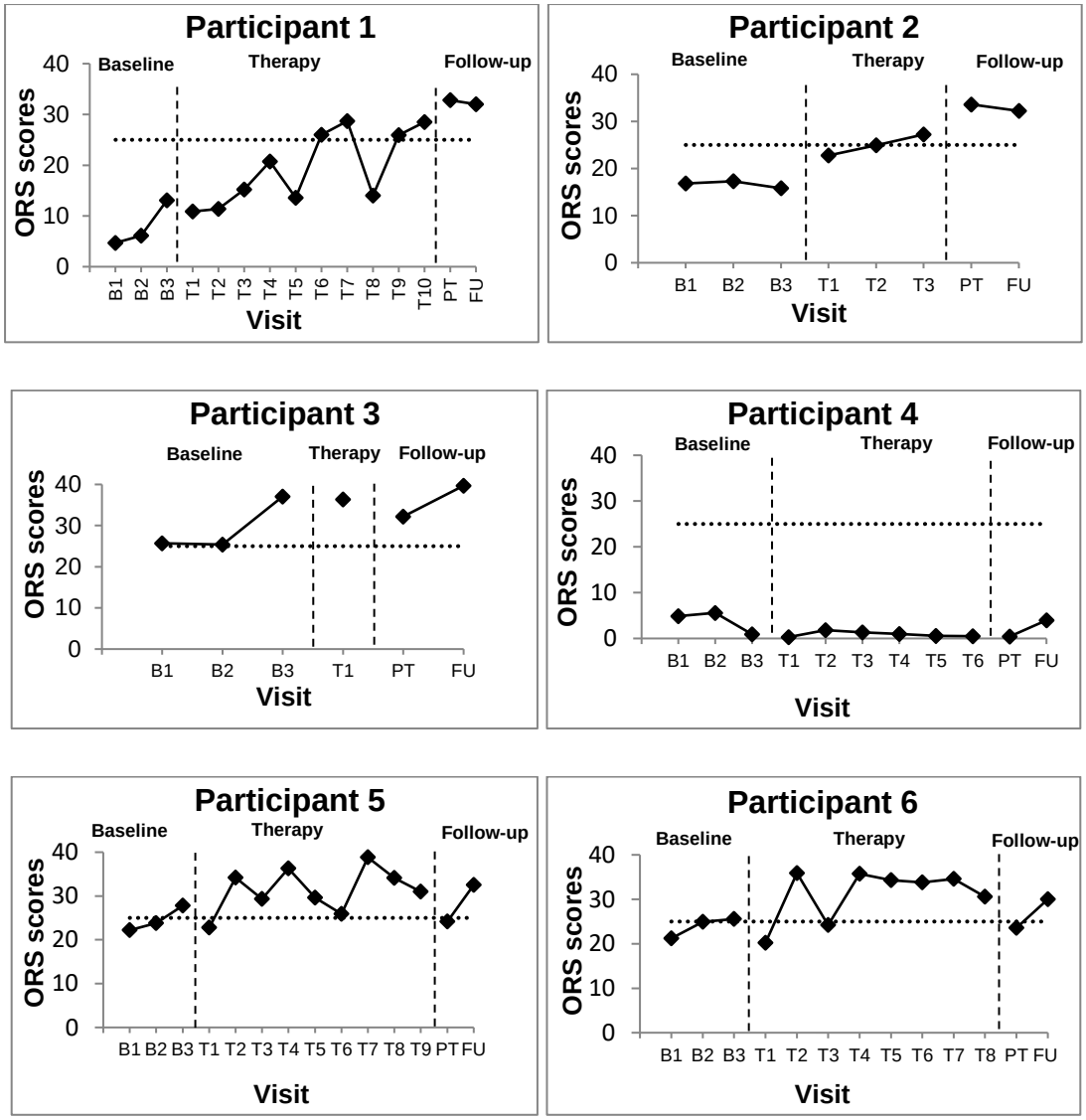

Figure 2: Changes to participants' scores on ORS.

The dashed horizontal line represents the clinical cut-off score (25). B1, B2: baseline at week 1, baseline at week 2. T: Therapy session. PT: post-therapy. FU: follow up (one month after PT).

Table 7: Changes to individual participants ORS scores.

	Baseline 1 (N=7)	Baseline 2 (N=7)	Baseline 3 (N=7)	Mean baseline (N=7)	Post-therapy (N=6)	Diff 1	1 month follow up (N=6)	Diff 2
P1	4.70	6.10	13.1	7.97	32.80	24.83	32.00	24.03
P2	16.80	17.30	15.8	16.63	33.60	16.97	32.20	15.57
P3	25.70	25.40	37.1	29.40	32.20	2.80	39.70	10.30
P4	4.90	5.60	0.9	3.80	0.40	-3.40	4.00	0.20
P5	22.20	23.80	27.8	24.60	24.20	-0.40	32.50	7.90
P6	21.20	24.90	25.6	23.90	23.60	-0.30	30.00	6.10
P7	19.30	18.80	19.7	19.27				

Diff 1: difference between the post-therapy and mean baseline score. Diff 2: difference between the follow-up and mean baseline score.

Participants' scores on the secondary measure CAPE for the frequency scores in the positive, negative and depressive dimensions are shown in Figure 3 (see Table S9 for supplementary data, Appendix O). One of the participants was unable to complete the CAPE due to an aversive emotional reaction to the items in the questionnaire. Participant 2 showed an improvement after therapy and participants 1, 2, and 3 showed an improvement at follow up on the CAPE frequency of positive symptoms dimension. On the CAPE frequency of negative symptoms dimension participants 1 and participant 5 showed a reliable and clinically significant improvement at follow up. On the CAPE frequency of depressive symptoms participants 1 and 5 showed a reliable and clinically significant improvement.

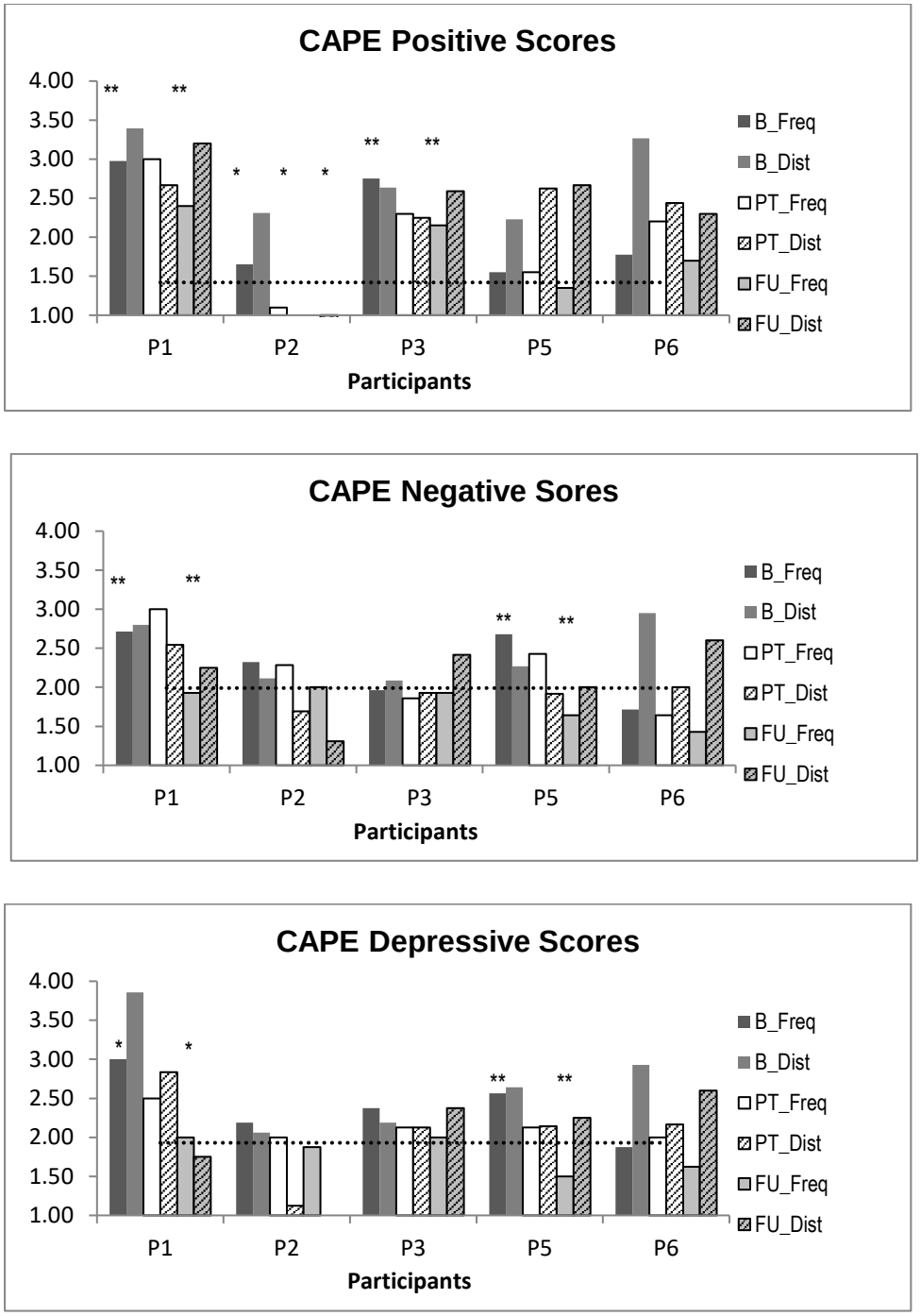

Figure 3: Participants' frequency and distress scores on CAPE Positive, Negative, and Depressive dimensions.
B_Freq: baseline frequency. B_Dist: baseline distress. PT_Freq: post-therapy frequency. PT_Dist: post-therapy distress. FU_freq: follow up frequency. FU_dist: follow-up distress. Dashed line represents the clinical cut-off score. * refers to reliable change, ** refers to clinically significant reliable change.

ROC scores (Figure 4) show an increase for four out of six participants. The score of participant 3 was already high at baseline and scores of participant 4 show a slight decrease from baseline (see Table S10 for supplementary data, Appendix O).

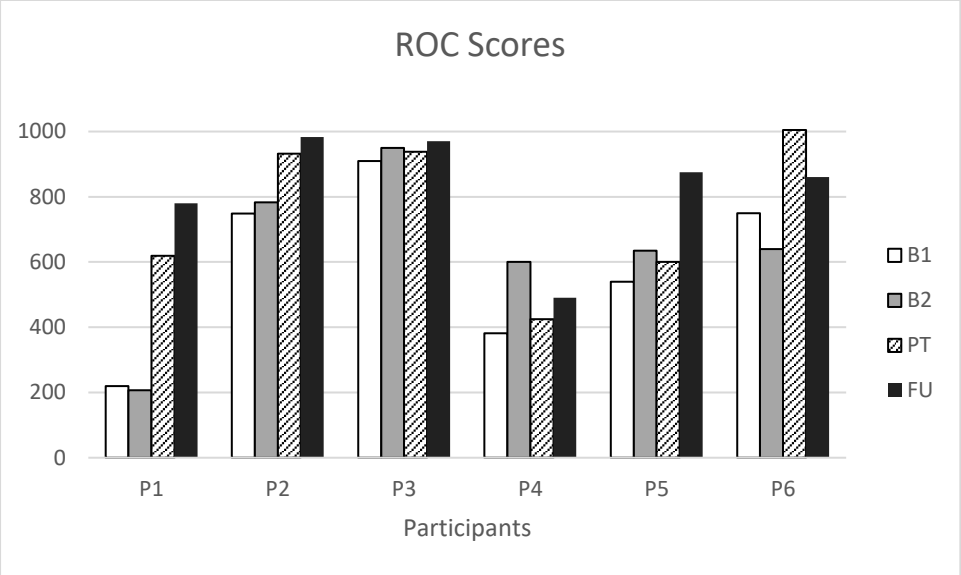

Figure 4: Participants scores on ROC. B1: baseline week 1. B2: baseline week 2. PT: post-therapy. FU: follow up.

4. Discussion

This study aimed to provide descriptive data regarding the way in which individuals experiencing non-affective psychosis respond to MOL in order to assess the effects of MOL on general functioning and symptoms of psychosis. All participants chose how many sessions they wanted to attend and all preferred to arrange the next session at the end of their current appointment. Six percent of all sessions booked were cancelled and rescheduled, and another 6% were missed (not attended without cancelling). These rates are similar to those found in other research of MOL therapy (Griffiths et al., 2019a). The numbers of not attended appointments reported in CBT literature vary from 15.9% (Mitchell & Selmes, 2007) to 8.9% (Binnie & Boden, 2016). The average SRS score of 37.94 indicated a good therapeutic relationship overall.

The results of the study, in terms of outcome measures, need to be interpreted with caution due to the small sample and the lack of a control group. The analysis of clinical significance was based only on participants who provided post-treatment ORS scores. Participant 7, who withdrew from the study after their first session, was therefore excluded, which could have overestimated the response to MOL therapy. Five out of the six participants who completed the study showed a statistically reliable improvement, and in four cases, the change was clinically significant. These

results are consistent with previous research of MOL therapy with ORS as an outcome measure, where patients achieved an average 8.96-point increase in scores (Carey et al., 2013). However, the trends in the changes in the ORS scores suggest that participants might have already been improving before the treatment began and the improvement noted at follow up cannot be attributed with any degree of certainty to MOL therapy. Variability in the ORS scores included a temporary worsening of scores for some participants after the first and last session. A subjective deterioration has been reported in other studies of psychological therapy (Brakemeier et al., 2014). Increased awareness and confusion resulting from enhanced reorganization has been offered as its explanation in MOL therapy (Mansell, Carey, & Tai, 2013). The lowering of ORS scores after the therapy ended corresponded with the rapid development of COVID 19 pandemic and the national lockdown in the UK. It is possible that the anxiety associated with the situation influenced participants' wellbeing and the ORS scores. The lack of improvement in participant 4, in addition to the withdrawal of participant 7 after the first MOL session, could suggest that some clients might not respond to MOL therapy favourably.

There was little evidence of change in the positive symptoms of psychosis as measured by CAPE. Three participants showed a reliable and clinically significant change in positive dimension of psychosis. Two participants experienced a reliable and clinically significant improvement in the negative symptoms, one in the depressive symptoms, and one participant improved but did not cross the clinical cut-off threshold in the depressive dimension. Overall, it appears that the majority of participants showed an improvement on a measure of wellbeing without a reduction in psychotic experiences. Research on recovery from psychosis, and other mental issues, does suggest that recovery from psychological difficulties is not necessarily tied to the symptoms, but involves a process of positive adaptation, finding meaning and satisfaction (Bellack, 2006). Indeed, the proposed mechanism of change in MOL therapy is reorganisation (Tai, 2009), leading to the resolution of conflict, as measured by the ROC. The scores on the measure of conflict reorganisation suggest that four out of six participants showed greater ability to use the components of reorganisation, such as facing the problem, increased understanding, awareness of new aspects of the problem and a change in perspective (Higginson & Mansell, 2008). This finding is consistent with changes in ROC scores observed in other

studies of MOL therapy (Churchman et al., 2019a; Griffiths et al., 2019a). The reorganization could have happened spontaneously for the participants as well as being promoted by MOL therapy.

Furthermore, only a minority of the MOL therapy sessions in this study were directly concerned with symptoms of psychosis. This is unsurprising in the light of the literature indicating that distress experienced by individuals with a diagnosis of a psychotic disorder stems from diverse, intra- and inter-personal difficulties, including identity, traumatic life experiences, interactions with health professionals and personal relationships (Griffiths, Mansell, Edge, & Tai, 2019b). Accordingly, qualitative research indicates that people value being able to decide on the content of their therapy sessions and to work on issues that are not directly related to their symptoms (Barkham, Gilbert, Connell, Marshall, & Twigg, 2005; Churchman, Mansell, Al-Nufoury, & Tai, 2019b; Griffiths, Mansell, Edge, Carey, Peel, & Tai, 2019c). A transdiagnostic approach that targets the mechanism underpinning all forms of psychological distress can be useful for this group of patients (Carey, Mansell, & Tai, 2015; Tai, 2016).

One participant who completed the study showed no change in ORS or ROC and was unable to complete the CAPE due to aversive emotional experiences evoked by reading the items of the measure. This difficulty in coping with negative feelings was also present during MOL therapy sessions and interfered with the participant's ability to engage in the therapy process. On the other hand, the participant whose ORS baseline score was above the clinical cut-off value also had high baseline ROC scores. Although it is difficult to draw conclusions based on two participants, these observations can be explained by the role of conflict reorganisation in reducing distress.

4.1. Limitations

The sample of the study was appropriate for its aims and similar to other case series (Searson et al., 2012; Taylor et al., 2019), however, it does limit the generalisability of the results. Lack of a comparison group precludes conclusions regarding the causal relationships between therapy and the outcomes observed. Baseline was short and some participants were showing a trend towards increased wellbeing before the intervention began. A longer baseline could have enhanced the comparison between

the phases of the intervention and the conclusions regarding the effects of MOL therapy. Therapy was delivered by one therapist who was also the researcher, thus increasing the possibility of bias. The study employed self-report measures of psychological wellbeing and symptoms of psychosis to reduce researcher bias, however, an assessment administered by an independent clinician may have been more impartial.

4.2. Conclusion

All participants who completed the study were able to make decisions regarding the number of therapy sessions and their content. The tentative positive results of this study in terms of the change in outcome measure scores call for further investigations of MOL therapy for people experiencing psychosis, with larger sample sizes and a control condition that would allow comparisons between MOL therapy and other therapeutic approaches.

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Paper 3: Critical reflection

This paper is a reflective piece and not intended for publication.

1. Overview

This paper expands on the context and rationale for the decisions made regarding the methods employed in the literature review and the empirical study, and discusses the strengths, weaknesses, and implications of the studies.

2. Choice of the research area

There are many psychological therapies that can be employed to assist clients in alleviating their distress. Even in those supported by considerable evidence base, however, a considerable proportion of people do not improve (Barkham, Stiles, Connell, & Mellor-Clark, 2012; Ehlers et al., 2013; Jauhar, Laws, & McKenna, 2019). These clients often attend all the scheduled therapy sessions, having spent a significant length of time on the waiting list. It was of particular interest to the author how psychological therapies and access to them can be improved.

3. Paper one – literature review

3.1. Topic selection

Choosing the topic for the systematic literature review was challenging. Perceptual Control Theory, from which stems MOL therapy – provides a framework for understanding human behaviour, as well as psychological distress and its resolution (Powers, 2008). Initial ideas for the literature review were focused on recovery from psychosis as one form of distress. An initial scoping exercise revealed an abundance of publications on this subject, so a metasynthesis of studies investigating recovery from bipolar disorder was considered. This idea was abandoned for two reasons: bipolar disorder was considered not closely related enough to the subject of the research and a metasynthesis had already been published the previous year. Whilst reading studies related to recovery, the researcher came across a fairly large body of research on the subject of missed appointments and drop out. The experience of clients missing appointments and the associated sense of frustration was familiar to the researcher from one of the placements. Following further discussions, it was decided that a review of client-led appointment scheduling – an important aspect of MOL therapy –would provide a useful contribution to existing knowledge.

The researcher conducted an initial scoping exercise within databases, and reviewed titles, abstracts and full texts of papers that investigated client-led appointment. It

became apparent that the publications on this subject within the area of psychological therapies were very sparse, despite a fairly large amount of studies of drop-out rates and non-attendance. It was therefore decided that a narrative synthesis of the findings would more appropriate.

Although narrative reviews and narrative syntheses can be perceived as lower quality than systematic reviews due to a greater risk of bias (Popay et al., 2006), the strengths and weaknesses of both approaches need to be balanced (Collins & Fauser, 2005). Where publications are sparse and include both quantitative and qualitative methods, as is the case of the review conducted in the current research project, the narrow focus of the systematic review would become a weakness. A narrative synthesis of literature searched in a systematic manner enables a wider scope, whilst preserving some of the strengths of the systematic search (Popay et al., 2006). Guidance for a good quality systematic literature review with a narrative synthesis specifies the components of such review, which ensure a comprehensive search of evidence, clear criteria for selection of studies, and appraisal of quality of the studies (Aveyard, 2014; Popay et al., 2006). It is believed that the literature review in this research project fulfils these criteria.

3.2. Search method

The choice of keywords that would result in a comprehensive but focused search was the greatest challenge of this part of the project. Initially the review question was broken down into three concepts: client-led approach, psychological therapy, and appointments. Clients' control over how many appointments they wish to attend is an integral component of MOL therapy. Accordingly, the initial choice of keywords was guided by the literature focusing on this approach. Alternative terms and synonyms were added to each concept (Table 8). This search revealed a very small number of studies (under a thousand) and did not include the relevant studies already known to the research team. In order to ensure that relevant papers were not omitted, the researcher conducted the search using different combinations of the three concepts. It became apparent that a good number of relevant papers appeared in the results after combining concept of client-led approach and psychological therapy, and many relevant papers were excluded from the results after the concept of appointments was added. There could have been several reasons for this. The small

number of publications on a subject might be associated with poor definition of the topic, with different authors using a wide variety of terms. In addition, the client-led approach might be discussed in studies implicitly, and thus can be difficult to capture with keywords. Consequently, the concept of appointments was abandoned, and further examination of the available literature revealed other terms, more specific, but less obvious ('partial booking'). These terms were added to the concept of client-led approach as their meaning included the idea of self-booking and client choice (Table 1). The concept of psychological therapy was also extended by the models recommended by NICE. The small number of studies on this subject and the challenges associated with finding an effective and comprehensive search strategy confirmed the importance of conducting a review of literature on client-led scheduling of therapy sessions.

Table 8: Database search terms used to identify studies related to client-led appointment scheduling in the initial search.

Client-led approach related words	**Psychological therapy related words**	**Appointment related words**
Patient-led, client-led, service user-led Patient choice, client choice, service user choice Patient control, client control, service user control	Counselling Psychotherapy Psychological therapy, psychological treatment, psychological intervention, cognitive behaviour therapy Mental health treatment, mental health intervention, mental health practice	Appointment, scheduling, sessions, booking

3.3. Screening

The search strategy was broad and rendered over 6000 titles, the vast majority of which related to patient choice in counselling employed in medical (physical health) settings, to choice regarding aspects of therapy other than appointments (e.g. choosing type of therapy, or the therapist), or to flexibility in the content of therapy. Although time consuming and at times somewhat overwhelming, the process of screening increased the researcher's familiarity with the subject area and provided reassurance that the likelihood of missing relevant papers was low.

3.4. Quality appraisal

The appraisal of the quality of studies is an important part of a systematic literature review as it helps to determine the risk of bias and prevent incorrect conclusions (Popay et al., 2006). The multitude of quality appraisal tools made it a challenging task to identify the most suitable one. Following the discussions with other trainees and the supervisor, the researcher chose a tool that can be applied to studies with quantitative, qualitative, and mixed methods, and includes criteria concerned with both methodology and reporting (QATSDD; Quality Assessment Tool for Studies with Diverse Designs) (Sirriyeh, Lawton, Gardner, & Armitage, 2012). Although QATSDD offers a range of scores from zero to three, rather than zero-one, in some cases it was still difficult to assign a definite score, partly due to the general nature of the scoring instructions (e.g. 1= Basic explanation for choice of analytical method, 2= Fairly detailed explanation of choice of analytical method, 3= Detailed explanation for choice of analytical method based on nature of research question). Reading a few published systematic reviews that used QATSDD (including some the studies included in the reviews) was helpful in establishing the level of detail required for particular scores. The researcher noted that assessing the quality of well-designed and well written studies took less time, and was more consistent between the two raters, than assessing the lower quality papers.

The final issue to resolve was the way the results of the quality appraisal would be used in the review. Considering that this was not a review of effectiveness of an intervention, it was not deemed appropriate to exclude studies with lower quality scores; rather, the scores were useful in assessing the strengths and limitations of the review and in forming conclusions.

3.5. Limitations, clinical implications, and future directions

The number of studies included is low and addition of other psychological therapies as comparators, as well as direct comparison of client-led and service-led approach in booking appointments, would increase the strength of overall evidence. It would also be prudent to investigate whether putting clients in charge of booking their first appointments could create a barrier in accessing therapy for some of them.

A strength of the review is the inclusion of a variety of studies, including pragmatic and benchmarking trials, which enhances the external validity of the investigated approaches. The findings suggest that adopting client-led approach to scheduling appointments in psychological therapy could reduce number of missed appointments, reduce waiting lists, and assist clients in improving their symptoms, thus reducing the gap between available services and demand. The findings of the review highlight the importance of employing a variety of designs, both quantitative and qualitative, in investigating psychological therapies and their different aspects.

4. Paper two- empirical study.

4.1. Design

The empirical study adopted a single case series design, in line with the hierarchy of evidence-based medicine (Rice, 2008). The existing research into MOL therapy consisted of controlled and uncontrolled pragmatic trials in primary and secondary mental health services (Carey, 2005; Carey, Carey, Mullan, Spratt, & Spratt, 2009) , a single case series in high school (Churchman, Mansell, & Tai, 2019), and a feasibility and acceptability RCT in first episode psychosis (Griffiths et al., 2019a). A single case design was deemed most appropriate for the purpose of investigating a novel therapeutic intervention in the context of limited available resources. Initially the aim of the study was to examine acceptability and feasibility of MOL therapy by completing the single case series and acquiring open-ended feedback from the participants following the intervention. However, following the review of the project the Research Sub-Committee advised that such scope of the project would exceed the available resources. The aims of the project were subsequently revised to obtaining descriptive data from the participants regarding the potential effectiveness of MOL therapy.

4.1.1. Measures

The choice of outcome measures was based on the balance of the burden of the questionnaires on the participants and acquiring a valid and meaningful measure of psychological wellbeing, symptoms, a putative mechanism of change in MOL therapy and therapeutic relationship. It was expected that participants might not experience symptoms of psychosis during the study, and consequently it was decided that the Outcome Rating Scale (ORS) (Miller, Duncan, Brown, Sparks, & Claud,

2003) would be the primary outcome measure. The brevity of the scale allows it to be used at baseline and at every session without overburdening the participant. An equally brief and straightforward measure, the Session Rating Scale (SRS) (Duncan & Miller, 2003), would be completed by the participants at the end of the session. As the researcher would be the person administering assessment measures and delivering intervention, thus increasing the risk of researcher bias, a self-report measure of psychosis was employed. The Community Assessment of Psychic Experiences (CAPE) (Stefanis et al., 2002) asksabout a good range of experiences and includes distress. Although CAPE was originally developed to investigate the incidence of sub-clinical psychotic experiences in the general population, it has since been utilized in clinical studies of psychosis. Finally, a short version of the Reorganisation of Conflict Scale (ROC) (Bird, 2013) was included as a measure of the mechanisms of change.

4.2. Recruitment

Achieving the recruitment target for the study (between six and eight people) was exceedingly difficult. The researcher had links with some of the mental health teams stemming from placements and expected the recruitment to be easier in those teams. The majority of the clinicians, including clinical psychologists, care coordinators, and psychiatrists, appeared enthusiastic and keen to ask their clients to be involved in the study. The researcher was supported by three clinical psychologists who facilitated liaison with other clinicians and advised on how the study should be presented to the mental health teams. Meetings were attended, some of them including presentations, both with whole teams and with individual clinicians, initially without success.

The original submission of the study to the NHS Ethics Committee proposed that clinicians would be asked to identify the potential participants and seek a verbal consent of their clients to be contacted by the researcher, who would then explain the study, provide the information sheet and meet the potential participants. It was hoped that this approach would reduce the added workload of care coordinators and allow the recruitment process to be as straightforward as possible. However, the Ethics Committee requested that a written consent should be sought from the clients. This requirement added time to the process of recruiting, although the research team

endeavoured to keep the forms as short and simple as possible. Care coordinators were provided with the written consent-to-contact forms and printed information sheets to give to interested clients. Once the client completed the consent-to-contact form, the researcher was able to contact them.

Reasons for the difficulty in recruiting people experiencing psychosis are varied. The current project competed for participants with other research projects investigating psychosis. Some clients are weary of potential negative impact of participating in research on their wellbeing, anxiety about the unknown, breaches of confidentiality, and a sense of wasted time or guilt should they need to withdraw (Kaminsky, Roberts, & Brody, 2003). In some cases clinicians can hold paternalistic attitudes to their clients and fail to provide them with information about research participation if they consider them too unwell (Howard et al., 2009). In addition, clinicians cited the unwillingness of their clients to take part in the study due to previous experience of psychological therapy or reported that those clients who were interested in participating were already receiving psychological therapy. Some clients expressed initial interest, which they withdrew after reading the information sheet. On the other hand, in some cases clients experiencing psychosis who were already on the waiting list for therapy were invited to take part in the current study and were consequently able to access therapy earlier than expected. The final sample of seven participants was recruited from three teams across three north west trusts.

The process of recruiting participants highlighted the importance of emphasising the potential contribution of the project to the existing knowledge and improving psychological approaches and of providing the mental health teams with feedback regarding the results of the study in order to encourage their future participation in research.

As a result of the difficulties with recruitment, following consultations with the supervisors, the researcher prepared and submitted an amendment to the project to include participants with all psychiatric diagnoses, however the Ethics Committee failed to respond to the submission for several months. In that time, the recruitment target for the study in its original design was achieved. However, since it was late in the research process, the study had to be truncated further, as there was no time to

complete the open-feedback interviews with the participants after the completion of the therapy.

4.3. Experience of delivering therapy

Training in MOL therapy was a major component of this study. Having read the manuals (Carey, 2006; Tai, 2016) the researcher completed several practice sessions with the supervisor, ST, and MOL therapy training workshop. During the summer months of the first and then second year the researcher also attended MOL therapy peer supervision and practice meetings. The task of learning a new psychological therapy was perhaps made harder by the need to acquire an appropriate level of competency in other approaches at the same time. Whilst the main therapeutic approach taught on the course is Cognitive Behavioural Therapy (CBT), the trainees often need to learn other modes of therapy (e.g. Acceptance and Commitment Therapy, Compassion-Focused Therapy) as part of their activities on placements. As a result, training in MOL involved not only developing a curious style of questioning, detecting disruptions and asking about them, and interjecting, whilst holding in mind the principles of conflict and reorganisation, but also inhibiting the already acquired rules of guided discovery as applied in CBT. On the other hand, the frequent observed practice combined with detailed feedback from advanced practitioners of MOL therapy was a very effective and efficient way of learning.

The researcher's experience of delivering therapy was different with every participant. Just a few initial sessions resulted in a considerable improvement in the researcher's ability to ask curious questions, although it was not clear whether the acceleration in learning was due to greater amount of practice or other factors. The curious questioning style was notably easier when the content of the session, led by the client, was less familiar to the researcher; highlighting the role of assumptions and their awareness on the part of therapist in helping the client to increase their understanding of the problem.

The researcher used individual and peer supervision regularly during the treatment window, especially for more challenging aspects of therapy. For instance, in some cases it was difficult to interject to ask questions, to ask about disruptions, or to keep the participant focused on one source of distress long enough to explore it. The conflict between goals or values underpinning participants' distress was easier to

discern in some cases than in others. When scoring the self-evaluation MOL therapy form the researcher felt that the area still needing improvement was asking about disruptions. All participants consented to have the sessions audio recorded, however one of them behaved differently when the recorder was on, compared to when it was switched off. Consequently, this participant's sessions were not recorded.

The researcher found that using the Session Rating Scale to enquire about how the approach could be improved encouraged participants to give feedback, enhanced transparency on the part of the therapist, and helped to improve the quality of the intervention. This is in line with evidence showing that monitoring client outcomes as well as the quality of the interactions benefit the clients (Reese, Norsworthy, & Rowlands, 2009).

The themes explored by the participants in therapy sessions were rarely concerned with the symptoms of psychosis and often centred around early life adversity, identity and relationships. This is consistent with research on causes of distress in psychosis (Griffiths, Mansell, Edge, Carey, Peel, & Tai, 2019b) and with the explanation of human behaviour and suffering provided by PCT (Powers, 2008). Overall, delivering MOL therapy and using supervision deepened the researcher's understanding of MOL therapy and PCT.

Initially all clients expressed a wish to attend appointments every week, even though in some cases they appeared to experience a level of ambivalence regarding this frequency. A few weeks into the treatment window some made decisions that they received a sufficient amount of therapy, and others began to schedule sessions at greater intervals, indicating perhaps an increased sense of being in charge of scheduling their sessions.

4.4. Analysis

Although the researcher was familiar with designing experiments and statistical analyses of quantitative data, analysing and presenting the results of a study conducted on six participants was a new challenge. It soon became apparent that the approaches taken in the published single case literature were varied. Some authors conducted inferential statistics analyses, whilst others focused on showing trajectories of individual participants' scores. It seemed clear that showing progress

of individual participants with the help of the criteria statistically reliable and clinically significant change was the most meaningful approach in such a small sample size (Jacobson & Truax, 1991). The analysis for the ORS was fairly straightforward thanks to the published literature on the clinical significance cut-off and the reliable change score. There were no such data available for analysis of CAPE score. The numerous studies using CAPE varied in their calculations and reporting of the scores (raw or weighted scores) and in the populations they studied. The majority of publications focused on young people at risk of developing psychosis and the clinical cut-off scores they proposed applied to that population (Mossaheb et al., 2012) or used raw scores (Boonstra, Wunderink, Sytema, & Wiersma, 2009), inappropriate when distress, as well as symptoms, is measured. The researcher decided to calculate the clinically significant and statistically reliable change criteria based on the formula provided by Jacobson and Truax (1991) and the data collected from the population similar in age and the length of psychosis to the participants in the current study.

4.5. Clinical implications and suggestions for future research

The difficulties with recruitment resulted in delayed commencement of the therapy window (November 2019). This delay meant that in order for the research process to be completed within the allocated time the open-feedback interviews with the participants could not be conducted. Exploration of participants' perspective on the intervention studied in future research would increase the strength of the conclusions and enable further positive development in psychological therapy. In addition, inclusion of control groups and larger samples would increase the explanatory power of the studies.

The current empirical study showed that people with a long-term experience of psychosis can benefit from a brief, transdiagnostic therapy, client-led therapy. The improvement and recovery, as measured with ORS, was generally not accompanied by changes in the level of symptoms. This suggests that future studies could benefit from administering measures that capture aspects of wellbeing not related to the symptoms as defined by the diagnostic manuals.

5. Personal reflections

Completing the two parts of this thesis included in this thesis provided me with different experiences. When thinking on the process of completion of this research project, my initial perception was that the literature review was more time- and labour consuming. On reflection, however, I realized that this impression was due to the greater variety of tasks and activities involved in completing the empirical part of the project. Perhaps interactions with others, from clinicians to receptionists and the participants, the different physical environments of the two mental health teams, and delivering therapy were more energising and stimulating, and so felt different that than the clearly delineated periods of time spent on reading, analysing and writing the review. Both parts of the project provided me with vital learning experiences.

The skills I gained through working with my research participants have considerably increased my clinical and professional competence. I am very grateful for the training and supervision I received both from my supervisor and the peer supervision MOL group during the project. During the first stage of training in MOL therapy, before the commencement of therapy with the research participants, I tried to grasp the different aspects of this therapeutic approach, and whenever I felt that I gained skills in one (e.g. asking about disruptions), another slipped from my awareness (e.g. asking curious questions). Once I started to feel that I had a basic level of competencies in those areas, trying to hold in mind the conflict that underpinned the person's distress so that it guided my questions, seemed to still elude me. As therapy within the research project progressed and I was able to explore aspects of it in supervision, as well as listened to the audio recordings and received detailed feedback, I felt that my understanding of MOL therapy and the theory underpinning it became much clearer. One area that still caused me difficulty was interjecting the participant in order to catch the fleeting background thoughts and ask about details of their experience. This was perhaps related to my own reactions to being interrupted in conversations, and to my anxiety about the participant's experience of therapy and the relationship I had with them.

Whilst the varied nature of this research study provided me with new learning experiences, as well as allowed me to develop my interest in MOL therapy, the difficulties with recruitment meant I had to write the papers alongside the final

placement. This stage of the project coincided with the COVID-19 pandemic and the ensuing lockdown, which was very anxiety provoking. The experience I gained from delivering therapy as part of this project became even more valuable as I had to switch to conducing placement activities from home, which meant less therapeutic work with clients. The level of self-discipline and focus that I applied to complete the current thesis on time exceeded that required in my previous research and work experience. I am very pleased about the choice I made when deciding on the project.

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Appendices

Appendix A: Publication guidelines for Clinical Psychology Review

CLINICAL PSYCHOLOGY REVIEW

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The final search string in Web of Science:

("client-led" OR "patient-led" OR "service user-led" OR client NEAR/5 choice OR patient NEAR/5 choice OR service user NEAR/5 choice OR client NEAR/5 control OR patient NEAR/5 control OR service user NEAR/5 control OR partial booking OR self-booking) AND ("psychological therapy" OR "psychological treatment" OR "psychological intervention" OR "mental health treatment" OR "mental health intervention" OR "mental health practice" OR counselling OR counselling OR psychotherapy OR "cognitive behav* therapy" OR "interpersonal therapy" OR "psychodynamic therapy" OR "mindfulness-based cognitive therapy" OR "Eye Movement Desensitization and Reprocessing")

The final search in PsycInfo and Medline:

(client-led OR patient-led OR service user-led OR client ADJ5 choice OR patient ADJ5 choice OR service user ADJ5 choice OR client ADJ5 control OR patient ADJ5 control OR service user ADJ5 control OR partial booking OR self-booking) AND (psychological therapy OR psychological treatment OR psychological intervention OR mental health treatment OR mental health intervention OR mental health practice OR counselling OR counselling OR psychotherapy OR cognitive behav* therapy OR interpersonal therapy OR psychodynamic therapy OR mindfulness-based cognitive therapy OR Eye Movement Desensitization and Reprocessing)

The final search string in CINAHL:

("client-led" OR "patient-led" OR "service user-led" OR client N5 choice OR patient N5 choice OR service user N5 choice OR client N5 control OR patient N5

control OR service user N5 control OR partial booking OR self-booking) AND (“psychological therapy” OR “psychological treatment” OR “psychological intervention” OR “mental health treatment” OR “mental health intervention” OR “mental health practice” OR counselling OR counselling OR psychotherapy OR “cognitive behav* therapy” OR “interpersonal therapy” OR “psychodynamic therapy” OR “mindfulness-based cognitive therapy” OR “Eye Movement Desensitization and Reprocessing")

Appendix C: Raters' agreement on quality appraisal

Case Processing Summary			
		N	%
Cases	Valid	42	100.0
	Excluded[a]	0	.0
	Total	42	100.0
a. Listwise deletion based on all variables in the procedure.			

Reliability Statistics	
Cronbach's Alpha	N of Items
.932	2

Intraclass Correlation Coefficient							
	Intraclass Correlation[b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.873[a]	.776	.930	14.752	41	41	.000
Average Measures	.932[c]	.874	.964	14.752	41	41	.000
Two-way mixed effects model where people effects are random and measures effects are fixed.							
a. The estimator is the same, whether the interaction effect is present or not.							
b. Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.							
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.							

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Edited By: Katherine Berry and Sandra Bucci

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Qualitative papers: 6000 words

Review papers: 6000 words

Special Issue papers: 5000 words

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Please refer to the separate guidelines for Registered Reports.

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Main text

References

Tables and figures (each complete with title and footnotes)

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Book

Bradley-Johnson, S. (1994). *Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school* (2nd ed.). Austin, TX: Pro-ed.

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Author Guidelines updated 28th August 2019

Appendix E: Outcome Rating Scale (ORS)

Outcome Rating Scale (ORS)

Name _____Age (Yrs):____ Gender_____
Session # ____ Date: _____
Who is filling out this form? Please check one: Self_____ Other_____
If other, what is your relationship to this person? _____

Looking back over the last week, including today, help us understand how you have been feeling by rating how well you have been doing in the following areas of your life, where marks to the left represent low levels and marks to the right indicate high levels. *If you are filling out this form for another person, please fill out according to how you think he or she is doing.*

Individually
(Personal well-being)

I----------I

Interpersonally
(Family, close relationships)

I----------I

Socially
(Work, school, friendships)

I----------I

Overall
(General sense of well-being)

I----------I

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Appendix F: Community Assessment of Psychic Experiences (CAPE)

CAPE
(Community Assessment of Psychic Experiences)

This questionnaire has been designed to measure certain feelings, ideas and mental experiences. We believe that they are much more common in the general population than was previously supposed, and that most people have had some such experiences during their lives.

Please answer the following questions as honestly as you can. The following pages have been divided into columns A and B. In column A, we would like you to circle the number which corresponds to how frequently during your life you have had each experience, and then in column B to indicate how distressing this experience is. If you answer NEVER in column A please move on to the next question.

There are no right or wrong answers, and there are no trick questions.

Please note that we are NOT interested in experiences people may have had when under the influence of drugs.

IT IS IMPORTANT THAT YOU ANSWER *ALL* QUESTIONS.

Column A example:

	0 Never	Sometimes 1	2 Often	Nearly Always 3
Do you ever feel as if people are reading your mind?	0	(1)	2	3

If you have answered *"sometimes (1)", "often (2)* or *"nearly always (3)"* for the question in column A, please circle the figure in column B that indicates how much distress you felt as a result of these thoughts, feelings and mental experiences. You then continue with the next question in column A.
If you have answered *"never (0)"* for the question in column A, then you do not have to answer the associated question in column B and you can continue with the next question in column A.

Column B example:

	Not distressed 0	A bit distressed 1	Quite distressed 2	Very distressed 3
How distressed did this experience make you feel?	0	1	(2)	3

We would appreciate it if you could complete the following questions:

Gender: ☐ male ☐ female

Date of Birth: _____

Level of Education: ☐ School (to 16 years) ☐ Degree/Vocational Qualification
☐ College (to 18 years) ☐ Post-graduate study

(Please tick the highest level of education that you have had)

Marital status: ☐ Single ☐ Cohabiting ☐ Married
☐ Separated ☐ Widow/Widower

Date filled in: _____
Code number *(to be filled in by research worker):* _____

If you score 1,2 or 3 in Column A go to column B.

If you score 0 in column A then go to the next question in column A.

How frequently have you had a certain thought, feeling or mental experience **during your life**?						**How distressing** was this experience?			
Column A						**Column B**			
	Never	Sometimes	Often	Nearly Always		Not distressed	A bit distressed	Quite distressed	Very distressed
1. Do you ever feel sad?	0	1	2	3	►	0	1	2	3
2. Do you ever feel as if people seem to drop hints about you or say things with a double meaning?	0	1	2	3	►	0	1	2	3
3. Do you ever feel that you are not a very animated person?	0	1	2	3	►	0	1	2	3
4. Do you ever feel that you are not much of a talker when you are conversing with other people?	0	1	2	3	►	0	1	2	3
5. Do you ever feel as if things in magazines or on TV were written especially for you?	0	1	2	3	►	0	1	2	3
6. Do you ever feel as if some people are not what they seem to be?	0	1	2	3	►	0	1	2	3
7. Do you ever feel as if you are being persecuted in some way?	0	1	2	3	►	0	1	2	3
8. Do you ever feel that you experience few or no emotions at important events?	0	1	2	3	►	0	1	2	3
9. Do you ever feel pessimistic about everything?	0	1	2	3	►	0	1	2	3
10. Do you ever feel as if there is a conspiracy against you?	0	1	2	3	►	0	1	2	3
11. Do you ever feel as if you are destined to be someone very important?	0	1	2	3	►	0	1	2	3
12. Do you ever feel as if there is no future for you?	0	1	2	3	►	0	1	2	3
13. Do you ever feel that you are a very special or unusual person?	0	1	2	3	►	0	1	2	3
14. Do you ever feel as if you do not want to live anymore?	0	1	2	3	►	0	1	2	3
15. Do you ever think that people can communicate telepathically?	0	1	2	3	►	0	1	2	3

If you score 1,2 or 3 in Column A go to column B.
If you score 0 in column A then go to the next question in column A.

How frequently have you had a certain thought, feeling or mental experience **during your life**?						**How distressing** was this experience?			
Column A						**Column B**			
	Never	Sometimes	Often	Nearly Always		Not distressed	A bit distressed	Quite distressed	Very distressed
16. Do you ever feel that you have no interest to be with other people?	0	1	2	3	►	0	1	2	3
17. Do you ever feel as if electrical devices such as computers can influence the way you think?	0	1	2	3	►	0	1	2	3
18. Do you ever feel that you are lacking in motivation to do things?	0	1	2	3	►	0	1	2	3
19. Do you ever cry about nothing?	0	1	2	3	►	0	1	2	3
20. Do you believe in the power of witchcraft, voodoo or the occult?	0	1	2	3	►	0	1	2	3
21. Do you ever feel that you are lacking in energy?	0	1	2	3	►	0	1	2	3
22. Do you ever feel that people look at you oddly because of your appearance?	0	1	2	3	►	0	1	2	3
23. Do you ever feel that your mind is empty?	0	1	2	3	►	0	1	2	3
24. Do you ever feel as if the thoughts in your head are being taken away from you?	0	1	2	3	►	0	1	2	3
25. Do you ever feel that you are spending all your days doing nothing?	0	1	2	3	►	0	1	2	3
26. Do you ever feel as if the thoughts in your head are not your own?	0	1	2	3	►	0	1	2	3
27. Do you ever feel that your feelings are lacking in intensity?	0	1	2	3	►	0	1	2	3
28. Have your thoughts ever been so vivid that you were worried other people would hear them?	0	1	2	3	►	0	1	2	3
29. Do you ever feel that you are lacking in spontaneity?	0	1	2	3	►	0	1	2	3
30. Do you ever hear your own thoughts being echoed back to you?	0	1	2	3	►	0	1	2	3

If you score 1,2 or 3 in Column A go to column B.
If you score 0 in column A then go to the next question in column A.

How frequently have you had a certain thought, feeling or mental experience **during your life**?						**How distressing** was this experience?			
Column A						**Column B**			
	Never	Sometimes	Often	Nearly Always		Not distressed	A bit distressed	Quite distressed	Very distressed
31. Do you ever feel as if you are under the control of some force or power other than yourself?	0	1	2	3	►	0	1	2	3
32. Do you ever feel that your emotions are blunted?	0	1	2	3	►	0	1	2	3
33. Do you ever hear voices when you are alone?	0	1	2	3	►	0	1	2	3
34. Do you ever hear voices talking to each other when you are alone?	0	1	2	3	►	0	1	2	3
35. Do you ever feel that you are neglecting your appearance or personal hygiene?	0	1	2	3	►	0	1	2	3
36. Do you ever feel that you can never get things done?	0	1	2	3	►	0	1	2	3
37. Do you ever feel that you have only few hobbies or interests?	0	1	2	3	►	0	1	2	3
38. Do you ever feel guilty?	0	1	2	3	►	0	1	2	3
39. Do you ever feel like a failure?	0	1	2	3	►	0	1	2	3
40. Do you ever feel tense?	0	1	2	3	►	0	1	2	3
41. Do you ever feel as if a double has taken the place of a family member, friend or acquaintance?	0	1	2	3	►	0	1	2	3
42. Do you ever see objects, people or animals that other people cannot see?	0	1	2	3	►	0	1	2	3

Thank you for taking the time to complete this questionnaire.

Appendix G: Reorganization of Conflict (ROC)

Reorganisation of Conflict Scale (RoC): Subscale

Please read each of the statements below and make a rating in the right hand column to indicate how much you believe each one. Make your rating by intersecting the line between 0% (don't believe this at all) to 100% (believe this completely). For example 50% means that the statement is 50:50, equally likely to be true or false for you. Here is an example:

EXAMPLE: I feel comfortable in my home

0 50 100

This would mean that you rate your belief that you feel comfortable in your home at 70% - it is not completely true (which would be 100%), but is more true than false for you (i.e. it is over 50%).

Please now make a rating for each of the following items. Try not to think too much about each item. There are no right or wrong answers to this questionnaire and only your own opinion counts.

		I DON'T BELIEVE THIS AT ALL		I BELIEVE THIS COMPLETELY
1	Talking through my problems helps me to feel different about them	0	50	100
2	In order to overcome a problem, I think that it is important to get a wider understanding of that problem	0	50	100
3	I accept that sometimes I may not have the answer to things right now and that is OK	0	50	100
4	When I consider a problem, I later become aware that I hadn't thought about it in that way before	0	50	100
5	I find that it helps to weigh up the pro's and con's of different things I could do to solve a problem	0	50	100
6	When I have a problem, I tend to face it to try to understand it better	0	50	100
7	Sometimes when I talk about a problem a different way of seeing it just comes to me	0	50	100
8	Once I've worked through a difficult time it feels like something has just shifted into place	0	50	100
9	When I've overcome a problem I notice that something has changed for me	0	50	100
10	I feel that it helps to just take a step back and look at your problems from a different perspective	0	50	100
11	When I have a problem I find myself listening to my thoughts to get a sense of perspective on them	0	50	100

Appendix H: Session Rating Scale (SRS)

Session Rating Scale (SRS V.3.0)

Name _____ Age (Yrs):____
ID# _____ Gender:_____
Session # ____ Date: _____

Please rate today's session by placing a mark on the line nearest to the description that best fits your experience.

Relationship

I did not feel heard, understood, and respected.	I----------I	I felt heard, understood, and respected.

Goals and Topics

We did *not* work on or talk about what I wanted to work on and talk about.	I----------I	We worked on and talked about what I wanted to work on and talk about.

Approach or Method

The therapist's approach is not a good fit for me.	I----------I	The therapist's approach is a good fit for me.

Overall

There was something missing in the session today.	I----------I	Overall, today's session was right for me.

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Appendix I: Consent form

A Case Series of Method of Levels (MOL) Therapy for People Experiencing Psychosis

Consent Form

If you are happy to participate please complete and sign the consent form below

	Activities	Initials
1	I confirm that I have read the attached information sheet (Version 1, Date 25/01/2019) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set. I agree to take part on this basis.	
3	I agree that any data collected may be published in anonymous form in academic books, reports or journals.	
4	I understand that data collected during the study may be looked at by individuals from The University of Manchester or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
5	I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study.	
6	I understand that there may be instances where during the course of the interview/therapy information is revealed which means that the researchers will be obliged to break confidentiality and this has been explained in more detail in the information sheet.	
7	I agree to take part in this study.	

Data Protection

The personal information we collect and use to conduct this research will be processed in accordance with data protection law as explained in the Participant Information Sheet and the Privacy Notice for Research Participants.

Name of Participant	Signature	Date
Name of the person taking consent	Signature	Date

Version 1; Date 25/06/2019
IRAS ID: 257300

	Activities	Initials
8	Optional: I agree to the MOL therapy sessions being recorded.	
9	Optional: I agree to the interviews being audio recorded.	

1 copy for the participant, 1 copy for the research team (original)

Appendix J: Risk protocol

PROTOCOL FOR MANAGING DISCLOSURE OF RISK

A Case Series of Method of Levels (MOL) Therapy for People Experiencing Psychosis

Rationale

During a session or other contact with the researcher a participant may indicate an intention to harm themselves or someone else. They might also provide information to the effect that a child or other vulnerable person may be in danger. Any information of this nature **must** be acted upon.

At the beginning of each meeting the participant will be informed that what they discuss with the researcher is confidential except if they indicate an intention to harm themselves or others, or if they provide information to the effect that a child or other vulnerable person may be in danger. In such situations, the researcher has a legal duty to break confidentiality.

If a participant indicates an imminent risk during a face-to-face or telephone contact with the researcher (either verbally or via their questionnaire responses), the following action will be taken.

Procedure

If the participant expresses an intention to harm themselves or others they will be reminded that the researcher has a duty to break confidentiality where risk is identified (as already outlined at the beginning of the interview). The researcher will conduct a risk assessment to ascertain the participant's intentions or plans of harming themselves or others. Depending on the level of risk, the researcher might then contact the participant's care co-ordinator/psychiatrist/named worker or GP. This action and its timing will depend on the urgency of the disclosed risk.

If the participant reports that they intend to harm themselves within the **next 48 hours,** i.e. they express an imminent risk, the session should immediately change focus to the imminent threat. However, if the participant reports that they intend to act on their thoughts in a few days, or longer, the researcher might continue with the session, review how the participant is feeling at the end of the session and call the care co-ordinator/psychiatrist/named worker following the completion of the session.

If the participant indicates that a child or other vulnerable person may be in danger the researcher will call the appropriate safeguarding team. If it is outside of 9am – 5pm and there is considered to be imminent risk to a child/vulnerable adult the police should be informed.

In either case the participant will be informed that confidentiality needs to be breached and will be encouraged to work in collaboration with the researcher to this end if possible.

The researcher will inform the participant of the planned action unless circumstances contraindicate this (e.g. there is risk to staff).

If the disclosure of risk takes place during a face-to-face contact and the researcher needs to inform the participant's named worker, the researcher might give the participant the option of making a phone call to their named worker themselves in the presence of the researcher or staying in the room whilst a call is made. The participant will also have the option to wait

in a safe place such as an adjoining room. The researcher will complete any agreed action assigned to them during the telephone conversation.

If the care co-ordinator/psychiatrist/named worker are not contactable a call should be made to the Duty worker for the appropriate Primary/Community Mental Health Team within the hours of 9am – 5pm Monday to Friday. Outside of these hours a call should be made to the Crisis Team or A&E. The researcher will act in accordance with any action plan agreed (e.g. accompanying the participant to A&E).

If the disclosure of risk takes place during a telephone contact, the participant will be informed that confidentiality will need to be breached. The same plan as above will be implemented and the participant should be called back to feedback the planned actions.

If the researcher is uncertain as to the appropriate course of action to take they should initially contact a research supervisor (Dr Sara Tai). If they are unavailable, the flow diagram of contacts should be followed.

In the unlikely event that all avenues are exhausted the researcher should follow the previously outlined plan (commencing with contacting the Care Coordinator).

If the participant poses a risk to the researcher, the researcher would immediately stop the meeting and is possible get themselves out of the room and into a more public space. If the risk was imminent, the researcher would immediately call the police. The researcher would contact the research team supervisor to discuss the risk and whether any further actions needed to be taken.

If the participant is currently harming him or herself or has done so recently, and there is a need for medical attention, it would be important to negotiate with the participant that they attend hospital or that they allow an ambulance to be called and call ahead to the psychiatric liaison team. The mental health team or duty psychiatrist would ensure that anyone refusing medical attention was assessed under the Mental Health Act. A decision regarding the need for a compulsory admission to hospital will then be made by an approved social worker in accordance with the Mental Health Act 1983.

If the participant or someone else admits to a serious previously unreported crime then it may be necessary to report this to staff or the police as soon as possible.

FACTORS TO CONSIDER IF A PARTICIPANT EXPRESSES HARM TO SELF OR OTHERS

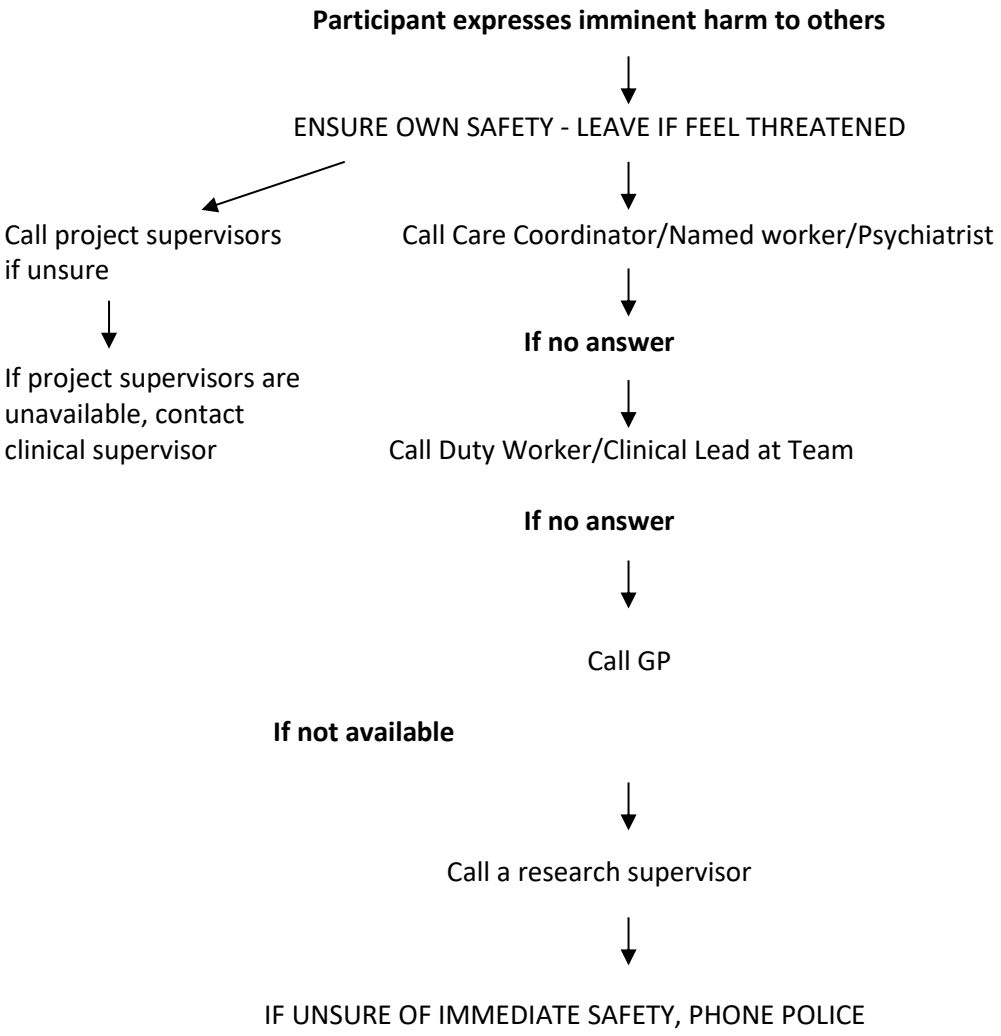
If a participant expresses ideas of harm to self or others these are important factors to consider and pass on:

- Ideation (frequency, intensity, duration, triggers)
- Plans/intent
- Access to means to carry out plans
- Timeframe
- Protective factors
- Access to support/isolation
- Hopelessness
- Drug or alcohol use
- Command hallucinations and perceived power or control over voices

Any concerns should be discussed with the project supervisor as soon as possible.

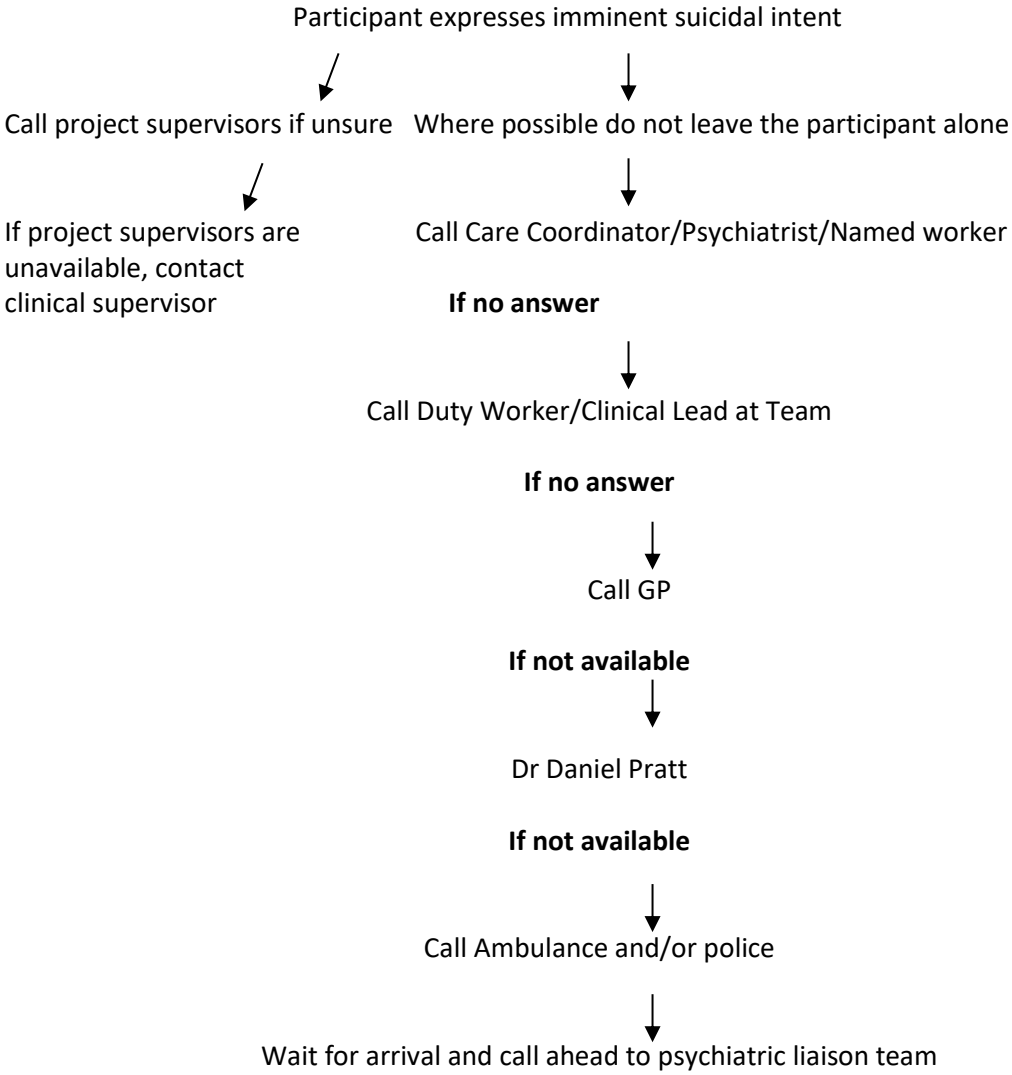
FLOWCHART OF CONTACTS FOR COMMUNITY PARTICIPANTS WITH IDENTIFIED INTENT TO HARM OTHERS

In situations where a Child / vulnerable Adult is at risk the appropriate Safeguarding Team should be contacted.



FLOWCHART OF CONTACTS FOR COMMUNITY PARTICIPANTS

WITH IDENTIFIED IMMINENT SUICIDAL INTENT



Appendix K: Ethical approval

North West - Greater Manchester East Research Ethics Committee
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8009

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 July 2019 (Revised 06 August 2019)

Dr Jadwiga Nazimek
Trainee Clinical Psychologist
Greater Manchester Mental Health Trust
University of Manchester, 2nd Floor, Zochonis Building,
Brunswick Street
Manchester
M13 9PL

Dear Dr Nazimek

Study title:	A Case Series of Method of Levels (MOL) Therapy for People Experiencing Psychosis
REC reference:	19/NW/0292
Protocol number:	N/A
IRAS project ID:	257300

Thank you for your letter of 4 July 2019, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, clinical trials are defined as the first four project categories in IRAS project filter question 2. For clinical trials of investigational medicinal products (CTIMPs), other than adult phase I trials, registration is a legal requirement.

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-rese arch-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilit ies/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

Notifying substantial amendments
Adding new sites and investigators
Notification of serious breaches of the protocol
Progress and safety reports
Notifying the end of the study, including early termination of the study
Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster_General]	1	25 January 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Manchester-2018-19]		07 May 2018
Initial Assessment for REC		
Interview schedules or topic guides for participants [topic guide]	1	27 March 2019
IRAS Application Form [IRAS_Form_16042019]		16 April 2019
Letter from funder [TAi_Sara_NHS001524_01.04.2019.IL]	1	01 April 2019
Letter from sponsor [Letter from sponsor]	1	01 April 2019
Other [Response to validation queries] Site confirmation: North West Boroughs Healthcare NHS Foundation Trust Pennine Care NHS Foundation Trust Lancashire Care NHS Foundation Trust		02 May 2019
Other [Consent to contact]	1	25 June 2019
Participant consent form [Consent form]		25 June 2019
Participant information sheet (PIS) [PIS]	2	25 June 2019
Referee's report or other scientific critique report		19 November 2018

Research protocol or project proposal [Protocol]	1	25 January 2019
Summary CV for Chief Investigator (CI) [Sara Tai brief CV]	1	02 April 2019
Summary CV for student [DV]	1	02 April 2019
Summary CV for supervisor (student research) [Sara Tai brief CV]		
Validated questionnaire [CAPE]	1	25 January 2019
Validated questionnaire [Outcome and Session Rating Scales]	1	25 January 2019
Validated questionnaire [The Reorganisation Factors Subscale]	1	25 January 2019

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/NW/0292 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Signed on behalf of Mr Simon Jones Chair

Email: nrescommittee.northwest-gmeast@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to Ms Lynne MacRae

Appendix L: Participant information sheet

A Case Series of Method of Levels (MOL) Therapy for People Experiencing Psychosis

Participant Information Sheet (PIS)

You are being invited to take part in a research study investigating a new psychological therapy for people experiencing psychosis. This study is part of the Doctorate in Clinical Psychology. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

Who will conduct the research?

Supervisor: Name: Dr Sara Tai Address: The University of Manchester 2nd Floor, Zochonis Building Brunswick Street Manchester M13 9PL Email: [redacted] Telephone: [redacted]	Trainee: Name: Dr Jadwiga Nazimek Address: The University of Manchester 2nd Floor, Zochonis Building Brunswick Street Manchester M13 9PL Email: [redacted] Telephone: [redacted]

What is the purpose of the research?

Psychosis refers to people having unwanted experiences (e.g. hearing, seeing, smelling, tasting or feeling things that other people do not, or having beliefs that others might find unusual). These experiences can be distressing. The most common treatment for psychosis is medication. Medication can help some people but it can have unpleasant side effects making it unacceptable for others. Another form of treatment is a psychological intervention called cognitive-behavioural therapy (CBT), although this also might not be

mental health problems have asked for more

ns.

Method of Levels (MOL), like CBT, is a psychological therapy. It focuses less on symptoms and more on the specific difficulties experienced by an individual. MOL therapy allows you time and space to talk through your problems and work out what is important to you. It is based on the idea that we become distressed when we cannot achieve the things that are important to us in life – usually because we need two or more things at the same time that are not compatible. For example, someone might need to feel independent but at the same time, feel scared about being alone. MOL aims to help you develop greater awareness of what is important to you so you can work out new solutions to balancing different priorities. The therapist asks questions to help you consider your problem in a different way and develop new perspectives and understandings that can lead to solutions.

This study aims to understand what people experiencing psychosis think about MOL and whether they find it useful. We will offer MOL therapy sessions only to people who take part in our study. At this stage MOL therapy is not available within routine NHS care.

Traditionally, when people are offered treatments such as CBT, there are a set number of appointments to attend. This study will investigate whether it is better for patients if they can decide themselves how many sessions of therapy they would like to have and how long their sessions should be.

You have been invited to take part in this project because you are 18 years old or over, have experienced psychosis and received support from a mental health service. We are looking for between 6 and 8 people to take part in this project.

- **Will the outcomes of the research be published?**

This research is being conducted as part of the Doctorate in Clinical Psychology at the University of Manchester for Trainee Clinical Psychologist Jadwiga Nazimek. It will be carried out under the supervision of Dr Sara Tai (Consultant Clinical Psychologist).

The findings will be written up for publication in a scientific journal and presented at conferences. All information will remain anonymous and you will not be identifiable in any reports or publications. We might use some of the direct quotes you make during the interview but it will not be possible to identify you.

- We will provide you with a summary of the overall study findings if you would like this.
- With your permission, your data collected in this study may be used to support future research. For example, the anonymous data files may be used in future studies or shared with researchers working on other studies. Any data used in the future will not contain your name or any other information that could identify you.
- **Who has reviewed the research project?**

The project has been reviewed by The University of Manchester Research Ethics Committee.

All research which involves NHS patients has to be reviewed by the National Health Service Research Ethics Committee (REC). This study has been reviewed by the North West Greater Manchester East Committee.

What would my involvement be?

- **What would I be asked to do if I took part?**

You will be invited to meet with the researcher who will answer any questions you might have and ask you to sign a form to say you consent to taking part. You will then be asked to complete three questionnaires about your symptoms, level of stress and your wellbeing. The questionnaires will take about 20 minutes to complete. Before you receive any MOL therapy, we will ask you to complete the questionnaires once a week for between two and six weeks. The reason we ask you to complete these questionnaires is to compare how you feel before MOL therapy with how you feel after you complete MOL treatment. Sometimes a person's mood and symptoms fluctuate. We ask you to complete the questionnaires between 2 and 6 times so that we have a better chance of establishing a baseline. You will receive £8 each time you complete the questionnaires to reimburse you for the time it takes.

Then you will be invited to have MOL therapy sessions with the researcher. At each session you can choose whatever aspect of your difficulties you want to talk about, and the researcher will ask you questions about the thoughts and feelings you are experiencing. You can choose how many sessions you would like to have - you can book up to one session of MOL a week for up to 12 weeks. The sessions will last up to 1 hour, but you can decide how long each session will be and you can end the session at any time. With your consent we will record the sessions on a University provided encrypted audio recorder so that we can ensure high quality of the therapy.

At the end of each session you will be asked to complete three questionnaires regarding how the therapy was for you, about your wellbeing in the last week, and about your thoughts related to the problem you were talking about. The questionnaires take approximately 8 minutes to complete. After 12 weeks you will be asked to complete again the three questionnaires, which ask about your symptoms, distress, and wellbeing, which takes approximately 20 minutes. When you finish your MOL therapy, you will be invited t an interview asking about your experience of the therapy. This interview will last up to approximately an hour. All the meetings will take place in a mental health clinic. Overall you might be involved in the study for up to 20 weeks.

It is possible that talking about problems can cause you distress. It is also possible that completing the questionnaires might raise issues that will distress you. The researcher will use her therapeutic skills to help you resolve any difficult feelings you might have so that you will not leave the research session in a distressed state. You can also speak to your care co-ordinator or contact voluntary and professional support organisations such as:

Samaritans	24 hour helpline	0161 236 8000
Saneline	4:30pm – 10:30pm	0300 304 7000
The Sanctuary	8pm – 6am	0300 003 7029

We cannot promise the research will help you but the information we will gather will help us understand how people with psychosis experience MOL therapy and whether it helps them. It is possible that MOL therapy sessions might be useful to you but we cannot guarantee that.

- **Will I be compensated for taking part?**

You will be reimbursed for the time it takes to complete the three questionnaires at the beginning and end of the study (£8 per week, for up to 6 weeks).

- **Do I have to take part?**

No, you do not have to take part in the study if you do not want to. Taking part in the research is voluntary; this means it is completely up to you to decide whether or not to join the study. Your decision to participate in this study will not be connected to the care you are receiving now or in the future.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you decide not to take part, you can inform the researcher by e-mail or telephone or in person, or you can inform your care coordinator and ask them to pass this information to the researcher. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

The MOL therapy sessions and the open feedback interviews at the end of the study will be recorded on a University provided encrypted audio-recorder. If you do not wish to be recorded you are free to decline. It is important that you are comfortable with the recording process at all times. If you are not comfortable at any point, you can let the researcher know and the recording will be stopped.

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Contact details
- Consent form will include your name and signature
- Age
- Gender
- Ethnic background
- Diagnosis of mental health
- Highest level of education
- Current employment status
- Current relationship status

The MOL therapy sessions and open-feedback interviews will be recorded on an audio-recorder. The audio recordings will consist of voice only. No personal information will be recorded on the questionnaires.

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with data protection laws which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research at http://documents.manchester.ac.uk/display.aspx?DocID=37095.

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The study team at The University of Manchester will have access to your personal information, but they will pseudonymise it as soon as possible. This means that your name and any other identifying information will be removed and replaced with a random ID number. Only the ID number will be recorded on the questionnaires. Only the research team will have access to the key that links this ID number to your personal information. Your consent form will be stored for 5 years after the date of any publication which is based upon it, to follow recommended good practice guidelines for research, in a secure locked cabinet at the University of Manchester.

The open-feedback interviews will be conducted by a researcher outside the study team. The researcher will be an employee or a student at the University of Manchester and will be trained by the study team to conduct the interviews. They will have access only to your contact details with your prior consent. They will not have access to any other data (e.g. the completed questionnaires).

If during the interviews or therapy sessions you indicate an intention to harm yourself or others, or if you provide information to the effect that a child or other vulnerable person

may be in danger, the researcher has a legal duty to break confidentiality. This is to ensure safety of yourself and others.

Any information you give to the researchers will not be shared outside of the research team in any other way without your consent.

Audio recordings of interviews will be transcribed by the member of the research team. Personal identifiable information will be removed in the final transcript. The recordings will be destroyed once they are transcribed. Audio recordings of therapy sessions will only be listened to by the researcher and the supervisor and subsequently deleted.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

- **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

Jadwiga (Jad) Nazimek
Trainee Clinical Psychologist

[redacted]

Tel. [redacted]

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Governance and Integrity Officer, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information at https://ico.org.uk/make-a-complaint/. Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher.

Jadwiga (Jad) Nazimek

Email: [redacted]

Tel. [redacted]

Appendix M: Demographic questionnaire

A Case Series of Method of Levels (MOL) Therapy for People Experiencing Psychosis

Demographic Information

1. Participant Code: (to be completed by researcher)

2. Age:

3. Gender

- ☐ Male
- ☐ Female
- ☐ Other: .....
- ☐ Prefer not to say

4. Ethnic background:

White

- ☐ English/Welsh/Scottish/Northern Irish/British
- ☐ Irish
- ☐ Gypsy or Irish Traveller
- ☐ Other: .....

Mixed / multiple ethnic groups

- ☐ White and Black Caribbean
- ☐ White and Black African
- ☐ White and Asian
- ☐ Other: .....

Asian/ Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ Chinese
- ☐ Other: .....

Black / African / Caribbean / Black British

- ☐ African
- ☐ Caribbean
- ☐ Other: .....

☐ Any Other Ethnic Group: .....

☐ Prefer not to say

5. Highest level of education received (e.g. University Degree, A-levels, GCSEs, O-levels, Secondary School)

6. Current relationship status (e.g. single, in a relationship but not co-habiting, co-habiting, married, separated/divorced, widowed)

7. Current employment status? (e.g. student, full-time employment, part-time employment, unable to work due to disability, unemployed, retired)

Version 1; Date 27/03/2019
IRAS ID: 257300

8. Have you ever been diagnosed with a mental health problem?

☐ **Yes** ☐ **No**

If yes, please provide details:

If you consider yourself to have any other mental health problems, please provide details below:

Appendix O: SRS, CAPE, and ROC Supplementary data figures and tables

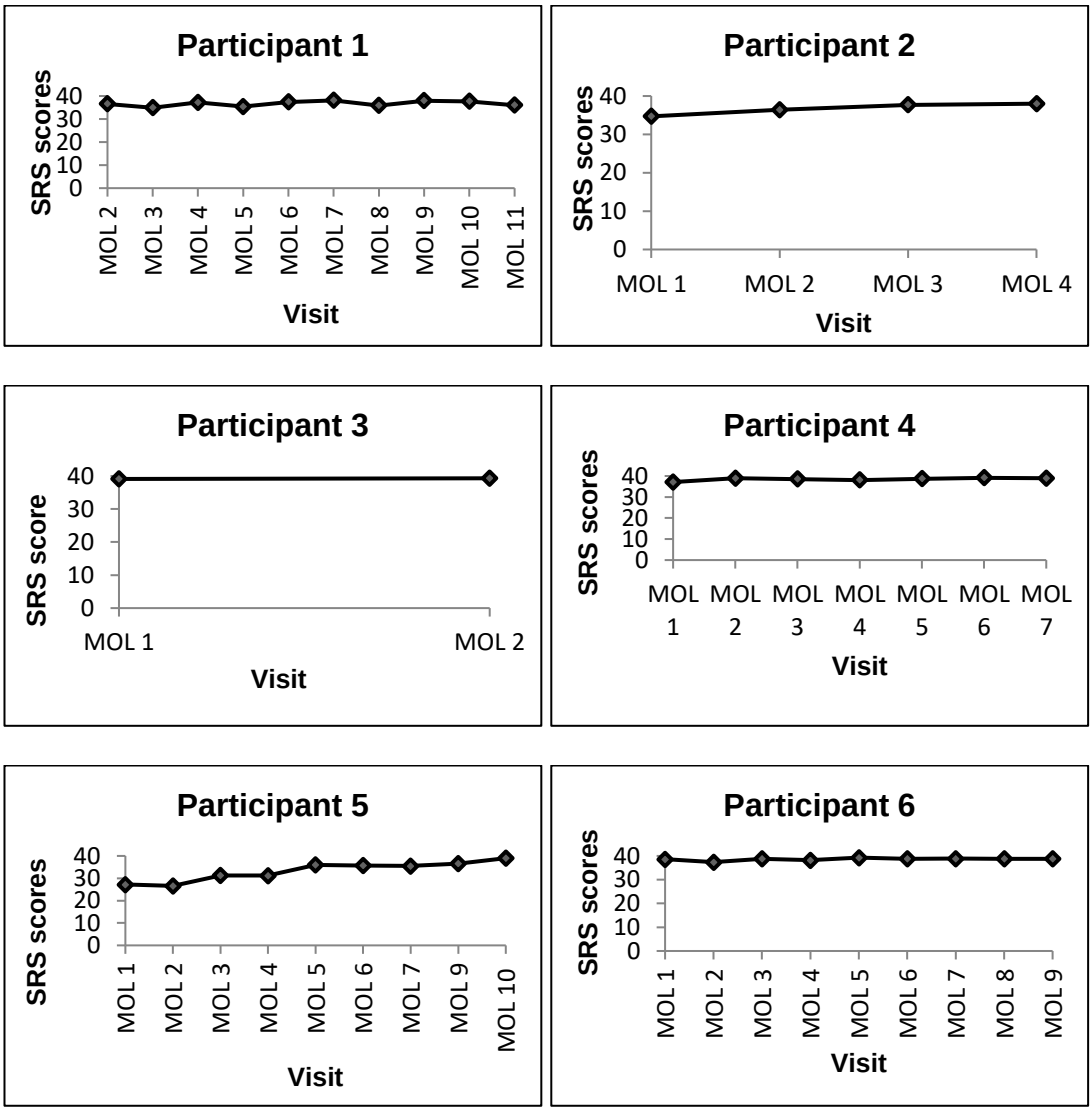


Figure S5: Participants' SRS scores.

Table S9a: Participants' overall CAPE frequency and distress scores.

	Mean Baseline		Post-therapy		Difference 1		1 month follow up		Difference 2	
	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress
P1	2.89	3.29	2.90	2.74	0.01	-0.55	2.17	2.71	-0.73	-0.58
P2	1.98	2.17	1.67	1.43	-0.31	-0.74	1.50	1.20	-0.48	-0.97
P3	2.42	2.38	2.12	2.12	-0.30	-0.27	2.05	2.49	-0.37	0.10
P5	2.12	2.35	1.95	2.19	-0.17	-0.16	1.48	2.37	-0.64	0.02
P6	1.77	3.09	1.98	2.26	0.20	-0.84	1.60	2.23	-0.18	-0.87

Difference 1: difference between the post-therapy and mean baseline score. Difference 2: difference between the follow-up and mean baseline score.

Table S9b: Participants' frequency and distress scores on CAPE Positive dimension

	Mean Baseline		Post-therapy		Difference 1		1 month follow up		Difference 2	
	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress
P1	2.98	3.39	3.00	2.67	0.03	-0.73	2.40	3.20	-0.58	-0.19
P2	1.65	2.31	1.10	1.00	-0.55	-1.31	1.00	0.00	-0.65	-2.31
P3	2.75	2.63	2.30	2.25	-0.45	-0.38	2.15	2.59	-0.60	-0.05
P5	1.55	2.23	1.55	2.63	0.00	0.40	1.35	2.67	-0.20	0.44
P6	1.78	3.27	2.20	2.44	0.43	-0.83	1.70	2.30	-0.08	-0.97

Difference 1: difference between the post-therapy and mean baseline score. Difference 2: difference between the follow-up and mean baseline score.

Table S9c: Participants' frequency and distress scores on CAPE Negative dimension

	Mean Baseline		Post-therapy		Difference 1		1 month follow up		Difference 2	
	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress
P1	2.71	2.80	3.00	2.55	0.29	-0.25	1.93	2.25	-0.79	-0.55
P2	2.32	2.12	2.29	1.69	-0.04	-0.42	2.00	1.31	-0.32	-0.81
P3	1.96	2.09	1.86	1.93	-0.11	-0.16	1.93	2.42	-0.04	0.33
P5	2.68	2.27	2.43	1.92	-0.25	-0.35	1.64	2.00	-1.04	-0.27
P6	1.71	2.95	1.64	2.00	-0.07	-0.95	1.43	2.60	-0.29	-0.35

Difference 1: difference between the post-therapy and mean baseline score. Difference 2: difference between the follow-up and mean baseline score.

Table S9d: Participants' frequency and distress scores on CAPE Depressive dimension.

	Mean Baseline		Post-therapy		Difference 1		1 month follow up		Difference 2	
	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress	Frequency	Distress
P1	3.00	3.86	2.50	2.83	-0.50	-1.02	2.00	1.75	-1.00	-2.11
P2	2.19	2.06	2.00	1.13	-0.19	-0.94	1.88	1.00	-0.31	-1.06
P3	2.38	2.19	2.13	2.13	-0.25	-0.06	2.00	2.38	-0.38	0.19
P5	2.56	2.64	2.13	2.14	-0.44	-0.50	1.50	2.25	-1.06	-0.39
P6	1.88	2.93	2.00	2.17	0.13	-0.76	1.63	2.60	-0.25	-0.33

Difference 1: difference between the post-therapy and mean baseline score. Difference 2: difference between the follow-up and mean baseline score.

Table S10: Participants' ROC scores.

	Mean Baseline	Post-therapy	1 month follow up
P1	213.5	619	780
P2	766	932	983
P3	930	938	970
P4	491	425	490
P5	587.5	600	875
P6	695	1005	860